IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	:Master File No. :2:12-MD-02327 :MDL No. 2327
THIS DOCUMENT RELATES TO THE CASES LISTED BELOW	:JOSEPH R. GOODWIN :U.S. DISTRICT JUDGE
Mullins, et al. v. Ethicon, Inc., et al.	2:12-cv-02952
Sprout, et al. v. Ethicon, Inc., et al.	2:12-cv-07924
Iquinto v. Ethicon, Inc., et al.	2:12-cv-09765
Daniel, et al. v. Ethicon, Inc., et al.	2:13-cv-02565
Dillon, et al. v. Ethicon, Inc., et al.	2:13-cv-02919
Webb, et al. v. Ethicon, Inc., et al.	2:13-cv-04517
Martinez v. Ethicon, Inc., et al.	2:13-cv-04730
McIntyre, et al. v. Ethicon, Inc., et al.	2:13-cv-07283
Oxley v. Ethicon, Inc., et al.	2:13-cv-10150
Atkins, et al. v. Ethicon, Inc., et al.	2:13-cv-11022
Garcia v. Ethicon, Inc., et al.	2:13-cv-14355
Lowe v. Ethicon, Inc., et al.	2:13-cv-14718
Dameron, et al. v. Ethicon, Inc., et al.	2:13-cv-14799
Vanbuskir, et al. v. Ethicon, Inc., et al.	2:13-cv-16183

OCTOBER 5, 2015

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CAPTION CONTINUED:

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Barr, et al. v. Ethicon, Inc., et al. 2:13-cv-22606
Lambert v. Ethicon, Inc., et al. 2:13-cv-24393
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Harmon v. Ethicon, Inc., et al. 2:13-cv-31818
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Tomblin v. Ethicon, Inc., et al. 2:14-cv-14664
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Cheshire, et al. v. Ethicon, Inc., et al. 2:14-cv-24999
Burgoyne, et al. v. Ethicon, Inc., et al. 2:14-cv-28620
Bennett, et al. v. Ethicon, Inc., et al. 2:14-cv-29624

OCTOBER 5, 2015

Deposition of MICHAEL P. WOODS, M.D., called for examination, taken pursuant to the Federal Rules of Civil Procedure of the United States District Courts pertaining to the taking of depositions, taken before SONDRA W. PETERSEN, RMR, CRR, CSR, Notary Public for the State of Nebraska, at Getman & Mills, LLP, 10250 Regency Circle, Suite 105, Omaha, Nebraska, on October 5, 2015, at 9:40 a.m.

A-P-P-E-A-R-A-N-C-E-S

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MONDAY, OCTOBER 5, 2015, OMAHA, NEBRASKA

P R O C E E D I N G S

-oOo-

MICHAEL P. WOODS, M.D.,
having been first duly sworn, was
examined and testified as follows:

DIRECT EXAMINATION

BY MR. KUNTZ:

Q. Please state your name for the record.

A. Michael Patrick Woods.

Q. And, Dr. Woods, I'm Jeff Kuntz. We met earlier. You understand we're here for a deposition that you've been named as an expert witness in the Mullins v. Ethicon case?

A. Yes.

Q. Before we get started, I want to ask you if you could write down on this piece of paper all of the complications you know of that relate to the TVT Retropubic mechanical cut device.

A. Unique to --

Q. No. Let me ask you this.

MR. SNELL: How about this. I'm going to object. Why don't you write them down if you want to ask him the question, Counsel.

MR. KUNTZ: I can ask him a question.

MR. SNELL: You can ask him the question, but you can write them down.

MR. KUNTZ: Okay.

MR. SNELL: This is not a writing deposition. This is an oral deposition.

Proceed.

MR. KUNTZ: Okay.

BY MR. KUNTZ:

Q. Doctor, tell me all of the complications that exist with the TVT Retropubic mechanical cut mesh.

A. What I need to have refined to me: Is it specific to TVT or to all Retropubic suburethral or colposuspensions?

Q. Okay. Let's start with all midurethral slings.

A. Both autologous and mesh type?

Q. Let's start with autologous.

A. With autologous -- and I would like to refer to the AUA -- I think that that -- excuse me here. I'm going to look through it because I think that gives a very nice comparison between the various ones, so that way we can look at their referenced.

Okay. This is Guideline for Surgical Management of Female Stress Urinary Incontinence 2009

Update from the American Neurologic Association.

And we're going to go first to autologous; is that correct?

Q. Sure.

A. And do you want --

Q. Are they listed on -- what page are they listed on?

A. This would be page -- doesn't have pages on it. I will have to go -- and I'll give you the appendix.

Q. Okay.

A. Appendix A11, Complication Rates un-prolapsed, and I'm going to go first with autologous fascia without bone anchors, and with -- with that, 4 percent transfusion rate infection --

Q. Doctor, I'm not asking for the rates. Just give me the complications that you believe are associated with it.

A. Okay. Infection, urinary tract infections, bladder injury, bleeding acute, bowel injury, wound infections, pain.

Now we'll go with without bone anchors. Again, bleeding requiring transfusion--and also on the other one bleeding requiring transfusion--infection, urinary tract infection,

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bladder injury, bleeding acute, urethral injury. They also have an other: And abdominal and vaginal wound infections.

Q. Okay. Any other complications you believe are associated with that type of procedure?

A. There was a dyspareunia rate, but I'm not able to locate that, so I will not speak to that at this point.

Q. Do you believe dyspareunia is a complication associated with a native tissue sling?

A. Yes.

Q. Okay. List all of the risks and complications related to a synthetic mesh sling that you believe exist.

A. Okay. What we have to do is also look at synthetic at the bladder neck versus synthetic midurethral sling. Also, you'd have to look at different types of meshes, but in this AUA Appendix A11 --

Q. Let's -- let me start, Doctor. Let's start with the Ethicon TVT Retropubic synthetic mesh. What are the complications associated with that device and that procedure?

A. All of the above.

Q. All of them that you listed for native

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tissue sling?

A. I believe that, but I'm going to look on the AUA.

Okay. So now what we'll do is we're going to go, again following their appendix from the AUA --

Q. Which appendix?

A. This would be A16, no prolapse.

At the bladder neck, also includes bladder injury and vaginal erosions. This is -- but this is not TVT. That is just at the bladder neck. TVT is a midurethral sling.

Q. So let me ask you this. Did the risks that you just named for at the bladder neck apply to the midurethral sling, as well?

A. Not nearly in the amount, so --

Q. And I'm not asking for percentage, Doc. This is a really simple question. Do you put the TVT Retropubic in still?

A. Yes.

Q. What do you tell your patients when they come to the office? A patient asks --

A. Okay.

Q. -- "Tell me all of the risks associated with this product," what would you tell them?

A. Bleeding, infection, scar tissue formation,

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damage to other organs that may or may not be recognized at the time of surgery, including bowel, bladder, ureters, great vessels, and the risk of mesh erosion in the vagina of about 1 percent and into the urethra or bladder at less than 1 percent.

Q. That's all of the warnings you would give them?

A. Correct.

Q. Okay. Is there any other risks that you know of that relate to the TVT Retropubic device made by Ethicon?

A. There would be, also, the risk not only with TVT Retropubic, but also other procedures, such as autologous sling or Burch, which would include nerve injury.

Q. Okay. Anything else?

A. Urinary retention.

Q. Anything else?

A. And voiding dysfunction.

Q. Anything else?

A. I cannot recall at this time.

Q. Okay. So every risk that you've listed out here in the last minute, including the list for native tissue repairs off Appendix 11, the risks you've listed off Appendix A16, and then the list you

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just named me are all of the risks that you know of that exist related to the TVT Retropubic device made by Ethicon?

MR. SNELL: Objection, compound.

Go ahead.

THE WITNESS: Also with any surgical procedures, there's risk of death.

BY MR. KUNTZ:

Q. Okay. Anything else, as you sit here right now? And you can add to it later if you want.

A. I may need to add to it later.

Q. Okay.

A. Again, when we talk about pain, I would also include dyspareunia.

Q. Okay. Anything else?

A. Voiding dysfunction. I got -- I may add to it later, but I can't recall off the top of my head now.

Q. Do you know if Ethicon had knowledge of any of those risks prior to the time it launched the TVT device --

A. Yes.

Q. -- Retropubic?

Okay. Do you believe it had knowledge of all of those risks at the time it launched the TVT

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device?
MR. SNELL: Objection, calls for speculation.
BY MR. KUNTZ:
Q. Well, let me ask you this. Have you reviewed any internal Ethicon documents or testimony of employees that talk about the risks they knew prior to the time the TVT was launched?
A. When I talk about -- I was asked to look at levels of evidence in evaluating the safety and efficacy for --
Q. I'm going to -- we can get into that and he can ask you. Just answer my question. Okay?
Do you know, as you sit here right now, whether Ethicon had knowledge of all of these risks that you've listed out prior to the time the TVT was launched?
A. Yes.
Q. Okay.
A. I have reviewed the internal documents; however, I've not allowed anecdotal, non-evidenced-based information to affect the safety and efficacy that I was asked to review.
MR. KUNTZ: Okay. I'll move to strike after yes.

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BY MR. KUNTZ:
Q. You can -- and you're going to say that over and over again, I know that, and Burt can ask you those questions, but just answer my question for now. Okay?
A. I'm aware of the internal documents.
Q. Okay. So the answer -- your answer is, yes, Ethicon knew of all of the risks that you listed out for me prior to the launch of the TVT?
MR. SNELL: Objection: Misstates, totally misstates. He said he's aware of the documents, but he did not consider that. You're misstating his testimony.
BY MR. KUNTZ:
Q. Okay. So you did not consider the Ethicon internal documents when forming your opinions that you're here to talk about today?
A. Absolutely not.
Q. Okay. So you don't rely on any Ethicon internal design documents in forming or giving your opinions today?
A. I am looking at the evidence-based data that's available.
Q. I think you just said, "Absolutely not." Did you rely on any Ethicon design internal documents

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in forming and rendering your opinions that you're talking about today?
A. No.
Q. How many -- when I talk about TVT Retropubic, I'm talking about the Ethicon product.
A. Yes.
Q. Okay. Do you understand that?
A. Yes.
Q. Okay. How many TVT Retropubic devices have you placed in your career?
A. Retropubic? A couple thousand.
Q. Okay. 2,000?
A. I would say plus or minus 500, yes.
Q. Okay. Do you keep track of that number?
A. I do not actively keep track of it anymore.
Q. Okay. When did you stop keeping track of it?
A. I'm still using Retropubic TVT, but I would say probably around 2007.
Q. Okay. So you kept track of how many TVT Retropubic devices you used up until 2007, correct?
A. 2007 or 2008.
Q. Okay. Where is that list?
A. I don't have it here.
Q. Okay. But you do have it, right? We can

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get a copy of it?
A. I'm pulling that off of my memory.
Q. Okay. So you do not have a formal list of how many --
A. No.
Q. -- TVT Retropubic devices you've kept (sic), right?
A. No.
Q. Okay. And up to 2007, how many devices -- how many TVT Retropubic devices did you place?
A. I probably placed about 12 or 13 a year.
Q. Okay. Is that from the first time you used it in 1999, I believe, to present date?
A. Yes.
Q. Okay. So -- and I apologize. I'm confused. So is 2,000 the total amount of just TVT slings in general you have placed, including TVT Secur, TVT-O?
A. No.
Q. Okay. So you -- it's your testimony that you've placed 2,000 TVT Retropubic devices?
A. Plus or minus about 500, yes.
Q. Okay. But you don't have any type of formal list documenting that?
A. No.

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Q. Do you perform your Retropubic TVT placement under general or local anesthesia?
A. I go to multiple different hospitals and so I have placed it under both general, regional, and local anesthetic.
Q. What's the majority of your placements done under?
A. Now it is sedation and local.
Q. What's the pore size of the Prolene mesh in the TVT Retropubic device?
A. It's an Amid classification Type I macroporous mesh that's greater than 75 microns.
Q. Why does Ethicon call the Prolene mesh the old construction mesh?
MR. SNELL: Objection: Form, foundation.
THE WITNESS: I'm not aware they do.
BY MR. KUNTZ:
Q. Okay. So as you sit here today, you didn't know that Ethicon calls the Prolene mesh using the TVT device the old construction mesh?
MR. SNELL: Same objection.
THE WITNESS: I am aware --
BY MR. KUNTZ:
Q. Do you know that or not?

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MR. SNELL: He's about to answer your question. Don't interrupt him.
THE WITNESS: I am aware that it is a mesh that has been utilized and studied extensively over the years, so the original studies looking at the Retropubic TVT are one of the older meshes, yes.
BY MR. KUNTZ:
Q. Okay. Have you ever heard it called the old construction mesh?
A. No.
Q. How many TVT Retropubic devices with laser cut mesh have you placed?
A. The laser cut came out I believe in 2007. And this is for Retropubic or all my TVT --
Q. Retropubics.
A. I really don't know. It depends on the hospital. When I open the package, it doesn't really matter whether it's laser cut or mechanically cut. I place it the same way.
Q. How do you know the difference?
A. I can actually see it because it's right in front of my eyes.
Q. Okay. Do you have any idea how many laser cut Retropubic devices you've placed?
A. No.

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MR. SNELL: Objection, form. Are you still talking TVT, because you just made a broad --
MR. KUNTZ: Yes.
MR. SNELL: You said "devices." You didn't say "TVT."
BY MR. KUNTZ:
Q. I'll tell you if I'm talking about something other than the TVT, like I said 10 minutes ago.
MR. SNELL: I will note that for the record. I just want a clear record, that's all.
THE WITNESS: No, I do not.
BY MR. KUNTZ:
Q. Okay. So you don't have any idea how many laser cut TVT Retropubic devices you've placed as we sit here today?
A. No, I do not.
Q. Okay. You don't keep track of the difference between mechanical cut mesh TVT Retropubics you place and laser cut?
A. No.
MR. SNELL: Hold on. Objection: Form, misstates. He already told you there's no difference in his opinion.
THE WITNESS: Would you please repeat

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that question.
BY MR. KUNTZ:
Q. Did you just testify that you can tell the difference between laser cut and mechanical cut mesh by looking at it?
A. Yes.
Q. Okay. Have you ever kept track or kept a chart of the differences in what you've placed, be it mechanical cut or laser cut?
MR. SNELL: Form.
THE WITNESS: No, because it --
BY MR. KUNTZ:
Q. Okay. And so as we sit here --
MR. SNELL: Hold on. He's not done answering. He's not done answering.
You can finish.
THE WITNESS: No. I can tell the difference when I see it. I do not track it and I do not feel it impacts my success rates --
BY MR. KUNTZ:
Q. Okay.
A. -- or complication rates.
Q. Okay. Have you ever tracked your complication rates as they may relate to laser cut mesh or mechanical cut mesh?

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A. No.
Q. What hospitals have you implanted mesh at since 2007?
A. Jennie Edmundson Hospital, Council Bluffs.
Q. In?
A. Council Bluffs, Iowa.
Q. Okay. And do you -- did you dictate to the hospital what mesh they should order, laser cut or mechanical cut?
A. No.
Q. Okay. Did you dictate to the hospital what product they should order?
A. I -- at all of my hospitals at that time were all using the Ethicon product.
Q. Okay. Did they use laser cut mesh at that hospital in the TVT Retropubic?
A. I do not recall.
Q. Okay. Who is in charge of purchasing at that hospital, do you know?
A. It would be the purchasing department.
Q. Okay. And they were in charge of purchasing all of the Ethicon product that you would use in surgery at that hospital?
A. And the other surgeons, yes.
Q. What other hospitals have you placed

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Ethicon products at since 2007?
A. University of Nebraska Medical Center; Denison Hospital -- or Crawford County Memorial Hospital in Denison, Iowa; Manning Regional HealthCare Center in Manning, Iowa; Audubon Community Hospital; Shenandoah Community Hospital.
Q. And did you dictate to any of those --
A. And Myrtue Memorial Hospital in Harlan, M-Y-R-T-U-E.
Q. Did you tell any of those hospitals which product to purchase?
MR. SNELL: Form.
THE WITNESS: I requested the Ethicon products.
BY MR. KUNTZ:
Q. Okay. Did you request laser cut or mechanical cut, specifically?
A. No.
Q. Again, you never kept track while you were at those hospitals which product you were using, be it laser cut or mechanical cut?
A. No.
Q. When was laser cut mesh first sold?
A. In the United States--I'm not positive on this--I believe it was around 2007.

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Q. Okay. How did you first learn about it?
A. I'm not sure.
Q. On Page 16 of your report, you state that -- go ahead and turn there.
You see on Page 16, that laser cut mesh was a marketing effort. Do you see that?
A. Yes.
Q. What do you mean by that?
A. I attended the TVT summits and we were asked, as a group, what did we think about this.
And you had physicians that were present that said, "I only want to use mechanical cut." I had physicians that said, "It really doesn't matter." And there were other physicians who were willing to try the laser cut. And that's, I believe, how I learned about it.
Q. Okay. What do you mean by marketing effort, though; what does that mean to you?
A. They asked -- they asked, "Do you feel that physicians would want to see this different?"
Q. Okay. So was it an effort to sell more slings?
A. No, I don't -- at that, they were just asking our opinion. I'm sure there's a marketing component, but they just asked our opinion.

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Q. In any of those TVT summits where they introduced laser cut mesh, did you ever talk to any physicians there that thought the two meshes were not the same?
MR. SNELL: Objection, lacks foundation.
THE WITNESS: If I were -- physicians always have their opinions, but what I -- what I do is I take -- I look at opinions, but what I -- when I'm looking at implanting something into a patient of mine, and in order to properly counsel them and provide the best care, I have to look at what the best evidence is. So I respect physicians' opinions, however that is very low on what determines how I do things.
BY MR. KUNTZ:
Q. Okay. And I'm going to ask you to answer my question. Were you -- when you were at any of those summits, did you ever talk to any physicians that felt that the laser cut mesh was different than the mechanical cut mesh?
A. I -- I'm sure I did. I just don't recall specific physicians at all.
Q. Have you ever reviewed any internal Ethicon documents that discuss there being a difference

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between the laser cut mesh and a mechanical cut mesh?
A. I believe that there were documents that did discuss a difference on it.
Q. Okay. And what difference was that?
A. That it was -- I have to look at the internal documents. Do we have the internal documents in --
Q. They're all right there, the ones you've reviewed.
A. Okay.
MR. SNELL: We have the thumb drive, too, if we need to get that out for you.
THE WITNESS: I apologize here. I must admit, there was just a huge amount of material to go through.
I don't see the internal documents in here.
BY MR. KUNTZ:
Q. Okay. We can go --
MR. SNELL: Do you want to look at it at a break?
MR. KUNTZ: Yeah.
MR. SNELL: He's got a thumb drive, so...
MR. KUNTZ: Yeah, we'll look at it at the break.

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MR. SNELL: What's that? Oh, that's not...
BY MR. KUNTZ:
Q. So you believe you've reviewed some internal Ethicon documents that talk about there being a difference between a mechanical cut and laser cut mesh?
A. From their benchtop. They were not surgeon specific, no.
Q. Have you ever reviewed any Ethicon internal documents that suggest that the Nilsson/Ulmsten long-term data should not be used to support laser cut mesh?
A. In that long-term data, because it was the old mesh, they can't use a laser cut in that.
Q. Okay. So you don't believe that the long-term data can support the laser cut mesh; is that what you said?
A. I believe that the longest-term studies, because it was not available, cannot.
Q. Okay. If I'm understanding you right, you're saying there's some doctors that might think it's different, but, in your opinion, it is not -- there's no difference between the laser cut and mechanical cut mesh?

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A. I have not --
MR. SNELL: Form.
Go ahead.
THE WITNESS: I -- in my own experience, I have not seen any difference.
BY MR. KUNTZ:
Q. What other products have you used for the treatment of stress urinary incontinence?
A. I have used TVT-O, TVT Abbrevo, TVT Secur, MiniArc, and Altis. Also, I have used peri-urethral bulking agents.
Q. What of the last one you said after MiniArc?
A. Altis.
Q. Who makes that?
A. Coloplast. I actually was in their FDA study.
Q. Okay. You -- I think you said in your report you started using midurethral slings in 1999 after monitoring the literature?
A. Yes.
Q. What literature?
A. This would have been Ulmsten's studies, also the studies out of Sweden where they looked at the multi-center studies, and, also, there was

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starting to be other data coming out of Europe that replicated that.
Q. Okay. So you believe there were studies out of the Scandinavian group and then the Swedish group?
A. And I -- there was also -- in going to different meetings and talking with surgeons, and everything, where it wasn't in the U.S. yet, I was very interested because I have done slings for -- ever since my second year of residency; and I was very excited to see the differences that could be happening.
Q. Do you agree that your knowledge regarding Prolene use in the hernia repairs was relevant in your original decision to use it in the pelvic floor?
A. No.
Q. Did you review the hernia literature on Prolene prior to using the Prolene sling?
A. I spoke with my general surgeon colleagues, and this was early on, where they felt that the polypropylene mesh, the macroporous mesh looked like it was better.
Q. Okay. So you relied on your general surgery colleagues who were using Prolene as part of your decision process in looking at the TVT sling

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made of Prolene?
A. Yes.
Q. Who were the authors of the Swedish papers that you first looked at in 1999?
A. Petros and Ulmsten were some of the authors. I'm terrible with names, so as we go through, I may have to look at some -- you know, some of those on that.
But one of the things that I was interested in was, actually, Amid classification. I had a mesh that I used intra-abdominally that migrated, and it really challenged me. And this was a Type III mesh. And when we were first doing slings and when I was in residency, we were looking at different ways, besides autologous, and we just did not have good results.
Q. Do you still use the Amid classification today?
A. Yes, I do.
Q. Have you read -- reviewed any literature that -- recent literature that discusses the relevancy of the Amid classification?
A. I did in selecting -- when TVT came out, was look at the Amid classification with macroporous mesh. I had a special interest because I had used Mersilene mesh, I had used Gore-Tex, I had used

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bovine dura mater. I had had numerous poor results.
Q. Right.
A. And the Amid classification made sense from a macroporous aspect, and so I was looking at that for part of my literature.
Q. And that's not what I asked.
Have you reviewed any recent literature discussing the relevancy of the Amid classification?
A. No, I have not.
Q. Okay. Have you reviewed any presentations from any of the incontinence groups regarding the relevancy of the Amid classification?
A. No, I have not.
Q. Okay. Have you reviewed any internal Ethicon documents that discuss their concerns about the Amid classification?
A. No.
Q. You said you used -- in what way did you use Gore-Tex previously?
A. I had used it suburethrally, in suburethral slings. Also, I used it -- there was some initial data on adhesion prevention; and I had also seen some of the literature in hernia, but it just did not work.
Q. Okay. When you were using Gore-Tex, you

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believed it was within the standard of care to do so, correct?
A. I believe that -- at that time, we were trying to figure out -- if I would do things differently today, I would absolutely be doing it an IRB-approved setting, and I wasn't at that level.
Q. Okay. My question was: When you were placing Gore-Tex, did you believe it was within the standard of care to place it?
A. Yes.
Q. Okay. Today, do you think it would be below the standard of care to place Gore-Tex --
A. Absolutely, for a midurethral sling.
Q. Okay. Same question with regard to Mersilene?
A. No. The erosion rate is very high.
Q. Okay. So when you were using it, you agree Mersilene was within the standard of care, correct?
A. Yes.
Q. And you'd agree today that it would be outside the standard of care to use Mersilene for a --
A. Yes.
Q. -- midurethral sling?
A. Yes.

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Q. Okay. Did you ever use the Proregion (ph) device?
A. No.
Q. Do you know how much Ulmsten has been paid by Ethicon?
MR. SNELL: Objection, form.
Go ahead.
THE WITNESS: Ulmsten is dead and --
BY MR. KUNTZ:
Q. Do you know how much Ulmsten's estate has been paid by Ethicon?
A. No, I do not.
Q. Okay. Do you know how much Ulmsten was paid by Ethicon when he was alive?
A. I saw something of $400,000 if the study could be replicated.
Q. Do you know in total how much Ulmsten was paid by Ethicon prior to his death?
A. No, I do not.
Q. Do you know how much his estate has been paid since his death?
A. No.
Q. Okay. Do you know how much Dr. Nilsson has been paid by Ethicon?
A. No, I do not.

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Q. Okay. You talked about migration of the mesh with Mersilene, I believe.
A. No, that was with the Gore-Tex.
Q. I'm sorry, with the Gore-Tex.
A. Yes.
Q. What are the complications from the migration of the Gore-Tex mesh?
A. In that case, there was no complications. It was just a woman had passed it per rectum three months after surgery.
Q. Okay. That's the only complications you saw from the migration of the Gore-Tex mesh?
A. That I have personally seen, yes.
Q. Okay. What other complications were you aware of from the migration of the Gore-Tex mesh?
A. I would say it was my personal experience in that one case.
Q. Okay. Have you ever reviewed any documents that suggest that the TVT mesh can migrate?
A. I am unaware of the TVT Retropubic sling mesh migrating.
Q. Okay. So you've never seen any documents or any study that suggests that the TVT mesh can migrate?
A. I have not seen any Level 1 studies,

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systemic reviews, or meta-analysis that show that it migrates.
Q. Okay. So you have not seen any studies, correct?
A. I have not seen any high-level studies.
Q. Okay. Have you ever seen any internal documents that suggest that it can migrate?
A. No, I do not recall.
Q. Do you know if Dr. Petros ever consulted or was ever paid by Ethicon?
A. Yes, Dr. Petros worked with Dr. Ulmsten.
Q. Do you know how much Dr. Petros was paid by Ethicon?
A. No, I do not.
Q. What current products are you using for the treatment of stress urinary incontinence?
A. I'm using Retropubic TVT, I'm using TVT Abbrevo, I'm using TVT-O. I have been using some of the MiniArcs just recently after the -- it showed clinical effectiveness similar to the Monarc. I use peri-urethral bulking agents, and plus I use the stage -- first stage which would be the pelvic floor and -- pelvic floor exercises, timed voiding techniques, behavior modification.
Q. When you say TVT Retropubic, are you

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talking about the original one or the Exact?
A. I've used -- I use both, depending on the hospital.
Q. Which hospital do you use the, I'll call it, classic TVT Retropubic?
A. It varies. Again, that is with purchasing, so whatever they hand me, I'm very comfortable using.
Q. Okay. Do you know which hospitals you're currently at use the classic as compared to the Exact?
A. No, I really can't say. It's just whatever they hand me when I do it. I really -- I really don't pay attention to which one it is.
Q. So you have no way to track which product you use more often currently?
A. No.
Q. What hospitals are you currently doing surgery at?
A. So it would be at the present time Myrtue Memorial Hospital, it would be Audubon Community Hospital, Manning Regional HealthCare, Shenandoah Community Health Center or Shenandoah Medical Center.
Q. And is purchasing at those hospitals responsible for what products are ordered for you to use in surgery?

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A. I would suspect so.
Q. Okay. Do you know who the purchasing agents are at each one of those hospitals?
A. No. No, I do not.
Q. Do they have a purchasing department?
A. Some of these are small hospitals. I don't even know if they have a purchasing department.
Q. Okay. Do you talk to anybody about purchasing there?
A. No. I just schedule my surgery.
Q. So you have no idea at those hospitals who's responsible for putting the product on the shelf?
A. Pretty much, yes.
Q. Okay. No idea?
A. Honestly, no idea.
Q. Okay. Do you know who the sales rep -- Ethicon sales rep is for those hospitals?
A. I'm not even sure who the Ethicon sales rep is.
Q. Who is your Ethicon sales rep?
A. I'm unsure. They've had a lot of turn- -- I don't know, I haven't seen them in quite a while. I haven't had an Ethicon rep in quite a while.
Q. So how many Ethicon products do you put in

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a week?
A. I would say, in a week, it could be anywhere from three to seven.
Q. Okay. And you have no idea who the Ethicon sales rep is for your area?
A. No, I don't.
Q. Okay. And you have no idea how those three to seven products get on the shelf?
A. They know when I schedule. That's -- that's all I care about is that the product is there when I get started.
Q. You agree that the TVT Exact only uses laser cut mesh?
A. Yes.
Q. Do you agree it's not sold with mechanical cut mesh?
A. I do not believe -- I'm not absolutely certain on that, but I do not believe it's mechanically cut.
Q. Okay. So as you sit here today, you don't know whether the TVT Exact is sold in mechanical cut mesh or not?
A. I do not recall seeing the mechanical cut, no.
Q. So is the answer -- do you know or do you

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not know?
MR. SNELL: Objection, form. He just told you. He's already answered this twice.
MR. KUNTZ: He said he didn't know, Burt.
MR. SNELL: No, he said --
MR. KUNTZ: I'm trying to find -- look --
MR. SNELL: Go ahead, answer him a third time. Tell him the same thing.
BY MR. KUNTZ:
Q. Do you know or not whether the TVT Exact is sold in mechanical cut mesh?
A. When I have it in my hand, I can tell. I don't pay attention if it's mechanical cut or not in placing the device.
Q. So the answer is you don't know?
MR. SNELL: Objection. He just told you he does know.
THE WITNESS: When I have it in my hand --
BY MR. KUNTZ:
Q. This is really simple, Doctor. Do you know whether the TVT Exact is sold in mechanical cut mesh or not? Yes or no question.

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MR. SNELL: Form.
THE WITNESS: I have not seen it in a mechanical cut.
BY MR. KUNTZ:
Q. You still didn't answer my question.
MR. SNELL: Yeah, he did. He just told you he hasn't seen a TVT Exact in mechanical cut.
MR. KUNTZ: That's a different question whether he seen it or not.
BY MR. KUNTZ:
Q. Do you know, as you sit here today, whether the TVT Exact is sold in mechanical cut mesh or not?
A. I do not believe, but I cannot say with 100 percent certainty.
Q. Thank you.
Doctor, have you ever said that the TVT Exact is an improvement over the TVT Retropubic classic?
A. No.
Q. Okay. You've never uttered those words?
A. When I placed the first TVT Exact, I was very surprised how easily it passed through the tissue. I don't know if I said it's better or not to be honest with you.

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Q. When did you place your first TVT Exact?
A. I don't recall the exact date. I know I was one of the first people in the area.
Q. Okay. And you've never said that the device is a definite improvement over the TVT classic?
MR. SNELL: Form.
THE WITNESS: If it would be the ease of passage, I might have said that because it surprised me in how quickly it passed through the tissues.
BY MR. KUNTZ:
Q. Okay. Have you ever said that the TVT-S was better than the TVT Retropubic?
MR. SNELL: Form. TVT Secur? I didn't hear your question. I'm sorry.
BY MR. KUNTZ:
Q. Have you ever said that the TVT -- you know what TVT-S is, don't you, Doctor?
A. TVT Secur, yes.
Q. Okay. Have you ever said that the TVT Secur was better than the TVT Retropubic?
A. I felt that it was equal.
And could I qualify that a little bit more?
Q. Sure.

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MR. SNELL: You can give your answers. Tell him your answer -- honest answers.
THE WITNESS: In many cases, there is still times when I've felt that the Retropubic was a better choice, depending on the clinical situation.
BY MR. KUNTZ:
Q. Do you know whether the MiniArc is mechanically cut or laser cut?
A. Honestly, I -- I don't know.
Q. Okay. Do you know the weight of the MiniArc?
A. Not off the top of my head.
Q. Do you know the pore size of the MiniArc?
A. I know it's a Amid classification Type I macroporous mesh.
Q. When did you first start using MiniArc?
A. Just recently. I was interested in a single-incision sling and the company had approached me. I went off for training. And I believe I have implanted probably four or five.
Q. You no longer use Ethicon single-incision sling because it's off the market, correct?
A. That's correct.
Q. Okay. Do you know why it was taken off the market?

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A. I believe that with the 522 studies that they felt that they would not proceed with its manufacture, but I don't know the exact reason they pulled it off.
Q. Do you know what a 522 order is?
A. The 522 order was that it is under increased scrutiny with the FDA and it allows for further evaluation. They have to do -- look at almost a PMA submission.
Q. Okay. Have you ever reviewed the 522 orders in this case -- or strike that.
Have you ever reviewed the 522 orders for the TVT Secur?
A. They were the same for all mini slings. I may have reviewed it at some time. I don't recall off the top of my head.
Q. Okay. And you've used the Prolift and the Prosima, as well, correct?
A. Yes, I have.
Q. And Prolift+M, correct?
A. Yes.
Q. Okay. And none of those products are no longer on -- strike that.
All of those products are now off the market, correct?

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A. They quit manufacturing them, correct.
Q. Okay. Were they all subject to 522 orders?
A. Yes.
Q. Okay. Did you review any of the 522 orders for any of those devices?
A. For Ethicon's products, no.
Q. Okay. Did you review any internal documents from Ethicon, including their responses to the 522 orders?
A. No, I do not recall.
Q. So four different Ethicon products that you once promoted and used are now off the market, correct?
MR. SNELL: Objection, form.
THE WITNESS: They quit manufacturing them.
BY MR. KUNTZ:
Q. Okay. And do you know why they quit manufacturing them?
A. That was a corporate decision. I am not privy to that.
Q. Okay. Do you believe it's still within the standard of care to place a POP kit?
A. I believe, in the appropriate situations, yes.

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Q. Okay. And what is the appropriate situation?
A. I believe that it's between the patient and the physician, and that the registries, especially for the studies, need to be done in order to be in compliance with the 522, and it should not be used as the primary repair --
Q. Okay.
A. -- in patients, more of a recurrence.
Q. Okay. So you agree it's below the standard of care to use a POP product for a primary repair?
MR. SNELL: Objection: Form, misstates.
BY MR. KUNTZ:
Q. Let me ask you. Do you -- let me restate. Do you believe it's below the standard of care to use a POP product for primary repair?
MR. SNELL: No, hold on. Hold on. Objection: Overbroad, misstates. If you want to hear why I'm objecting --
MR. KUNTZ: I don't care. I don't care. You can have the objection for the record. That's fine.
MR. SNELL: You say POP product, then.

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BY MR. KUNTZ:
Q. Okay. We'll go through each one, Doctor. Do you believe that it's below the standard of care to place a Prosima for a primary repair?
A. It would depend -- it would actually depend on the patient characteristics, and if you had somebody that had a connective tissue disorder, it might be warranted.
I feel that in most instances that using either a native tissue repair, there would be other people that would consider sacrocolpopexy as a repair, but I think that has to be individualized between the surgeon and the patient. So there will always be instances where I cannot say a blanket statement.
Q. Okay.
A. I just --
Q. Same answer for Prolift?
A. Yes.
Q. Same answer for Prolift+M?
A. Yes.
Q. Ethicon paid you to do a study on TVT Secur, correct?
A. That is correct.
Q. Okay. And they provided the product for

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free?
A. Yes, they did.
Q. And you reported positive findings for the TVT Secur?
A. Yes, I did.
Q. Why didn't you present the five-year data from the TVT Secur?
A. The -- actually, did I present -- the design of the study was actually a six-month study, and then I continued to have contact with these patients and followed up with UDI scores over a longer term. That was outside of the study; it was a continuation that was funded by myself.
Q. Okay. So the study was only designed to be a six-month study?
A. It was a feasibility study, could it be done.
Q. Did it track complications?
A. Yes.
Q. Okay. Couldn't track long-term complications, could it?
A. It was not designed for that effect.
Q. Okay. How long does a study have to be to track long-term complications, in your mind?
A. Ideally, the International Continence

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Society recommends three to five years.
MR. KUNTZ: Let's take -- can we take a quick break?
MR. SNELL: Sure.
THE WITNESS: Okay.
(10:26 a.m. to 10:35 a.m. - Recess taken.)
(Exhibit No. 1 marked for identification.)
BY MR. KUNTZ:
Q. Doctor, I'm going to that hand you what's been marked Exhibit No. 1. Have you seen this document?
A. Yes.
Q. Okay. Did you review the document request in Schedule A on Page 5 of this document?
A. Yes.
Q. Okay. And you brought some documents that we'll go through and mark later that are here on the table.
Did you look at all of these and bring responsive documents that you have?
A. Yeah, any ones that I have, but I don't have most of these.
Q. Okay. Well, let's go through -- let's go

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through it.
Obviously, you brought your CV.
A. Yes.
Q. Okay. Did you bring all of the documents that were provided to you or which were used to form your opinions?
A. Yes.
Q. Okay. And that's in the notebook and on the thumb drive?
A. Yes.
Q. And some loose-leaf studies that we have here?
A. Yes. And some of them are repetitions.
Q. No. 5, you haven't reviewed any depositions in this case, have you?
A. I have been provided depositions from the plaintiffs, and -- I don't remember. Is it Blaivas?
MR. SNELL: Just tell him -- you have to answer his questions to the best of your ability, so tell him what depos you reviewed. That's what he's looking for.
THE WITNESS: Okay.
BY MR. KUNTZ:
Q. Okay. Well, let me ask you this. I didn't see any depositions. I don't -- it's unclear, but on

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your reliance list, there's not any depositions listed but maybe a deposition of Gene Kammerer. Do you know who Gene Kammerer is?
A. No.
Q. Okay. Did you review a deposition of Gene Kammerer?
A. Not that I recall.
Q. Okay. Did you review any depositions of any Ethicon employees?
A. Not that I recall.
Q. Okay. What depositions did you review prior to today?
A. Blaivas, Elliott. What's the guy in Chicago? Ro- --
Q. Rosenzweig.
A. Yeah, Rosenzweig. And Marc Toglia.
Q. And have you provided all of your time sheets to defense counsel in this case?
A. Yes, I have.
Q. How much time have you spent reviewing this case?
A. About 100 hours.
Q. That includes up to today?
A. No.
Q. Okay. What does the 100 hours include?

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A. Reviews of when I took my board review course, looking through textbooks, going through old documents, old publications, trying to find different things. I've been reviewing this literature since 1987, '88, in a continuous fashion and going through and trying to find older documents on why I did the Burch and these kind of things.
Q. Okay. How many times have you met with defense counsel on this case?
A. Is it twice or three times? Two or three times. I'm not sure -- I'm trying to remember.
It would be three times --
Q. Okay. Were these all-day meetings?
A. -- face-to-face.
No.
Q. Okay. Half-day meetings?
A. The first time was a half-day, yesterday was a half-day. It -- I need to ask.
THE WITNESS: I believe I've met with you three times. I don't --
MR. SNELL: You have to -- hold on. You have to answer his questions. He's -- don't worry about --
THE WITNESS: Okay.
MR. SNELL: -- what my recollection

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is.
THE WITNESS: I --
MR. SNELL: Only give him your honest answer --
THE WITNESS: I --
MR. SNELL: Hold on, listen. Listen, Dr. Woods. You're here to answer his questions honestly and truthfully to the best of your ability and knowledge. You do that. If you don't know something, you tell him, "I don't know," but answer his questions to the best of your knowledge and recollection.
THE WITNESS: Two or three times.
BY MR. KUNTZ:
Q. There's -- I can only dream of the day that I get to depose Burt, but it probably will never happen.
MR. SNELL: I might be deposing you. You would be in trouble.
MR. KUNTZ: We can only dream, but...
THE WITNESS: Okay.
BY MR. KUNTZ:
Q. Okay. So two or three days.
How many phone calls did you have?
A. One phone call.

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Q. Okay. So you only talked to defense counsel one time, over the phone?
A. Yes.
Q. Okay. And you provided -- so you spent 100 -- and I apologize if I asked, but you spent 100 hours or submitted a bill for 100 hours?
A. Yes.
Q. Okay. And that -- does that include your meeting yesterday?
A. No.
Q. Okay. Does it include the previous meetings?
A. That would be -- I believe that that was on the day two, September 25th.
Q. Okay. So since September 25th, you've had one meeting with defense counsel?
A. That is correct.
Q. Okay. And how much other time, besides the meeting, have you spent since September 25th preparing for this deposition?
A. I would have to look on my cheat sheet, which I don't have with me.
Q. Okay. Do you keep your cheat sheets?
A. I just write down, and when I submit, toss. And then I'm just trying to keep a record.

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Q. Okay.
A. I'm trying to be very honest on how much time I spend.
Q. Okay.
A. And so if I have a 15-minute break and I look at something that's pertinent to this, I will do that. I have a very busy practice and, also, I've assumed some other positions recently, and so my time has been very scattered over the --
Q. Okay.
A. -- last couple of weeks.
Q. Do you keep -- do you -- do you still have your -- what you call your cheat sheet for your 100 hours up to September 25th?
A. No, I do not.
Q. Okay. You do have your cheat sheet from September 25th to today?
A. I have multiple little sheets somewhere --
Q. Okay. All right.
A. -- either at home or at work.
Q. We can get a copy of those, can't we?
A. Yes.
Q. Okay. Just ballpark, how many hours do you think you've spent since your 100 hours September 25th bill and this morning?

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A. I'm going to ballpark: Probably 15 to 20 hours.
Q. Okay. And what do you charge an hour?
A. In this here, because I -- let me go here because I don't pay the most attention. I believe it is $550 an hour.
Q. Is that across the board for record review and deposition time?
A. Deposition time is $650 an hour.
Q. Okay. And what's trial time?
A. $4,000 per day.
Q. Okay. Does that include expenses, or are expenses separate?
A. The answer is, I haven't thought about it.
Q. Okay. Have you ever testified at trial?
A. I have testified at one trial.
Q. Okay. What type of case was that?
A. That was an overactive bladder case after a back injury.
Q. Okay. Were you an expert witness in that case or a defendant?
A. I was for the plaintiff.
Q. Where was that case pending?
A. That was in Nebraska City.
Q. And I'm sorry if I asked. Was it a medical malpractice case?

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A. Actually, it was a personal injury case.
Q. Involving -- is that the car wreck case?
A. Yes.
Q. Okay. That's the one you've listed on your --
A. Yes.
Q. -- on your report?
A. In all honesty, I don't try to do this stuff.
Q. Have you -- look at No. 12.
A. Let me get my glasses here. I apologize.
Q. No. 12 on Page 7 of the notice.
MR. SNELL: Oh.
MR. KUNTZ: I'm sorry. Do you need a copy?
MR. SNELL: No, just -- okay.
THE WITNESS: Okay.
BY MR. KUNTZ:
Q. You've been a consultant for Ethicon for many years, correct?
A. Yes, I have.
Q. Okay. Did you attempt to bring any of the consulting agreements you have with Ethicon?
A. I don't have any of those. When I moved my

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office, any of those that were old, I tossed out.
Q. Okay. When did you move your office?
A. 2013.
Q. Okay. So do you have the ones from 2014 and '15?
A. I'm not a consultant. I don't remember the last time that I've worked with Ethicon. It was probably 2013. I am not -- I am not exactly sure on that.
Q. So you haven't received any payments, non-litigation, as a consultant, from Ethicon in 2013 or '14?
A. I believe in 2013 I did one -- one or two educational things for sales staff.
Q. Okay.
A. But I don't recall 2014, to be very honest with you.
Q. So you did consult with them in 2013?
A. First part, yes.
Q. Okay. In 2014, it's your testimony that you did not consult with Ethicon?
A. I do not recall having a consulting agreement with Ethicon.
Q. Okay. Well, on your CV, it says, Consult for Johnson & Johnson, Ethicon's Women's Health and

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Urology, 2004 to 2014?
A. The first part of 2000 (sic), so January 1.
Q. Okay.
A. I don't know when the last consulting agreement ended, but I think it was the end of 2013.
Q. Okay. So you haven't done anything in that calendar year 2014 for Johnson & Johnson?
A. Not that I recall.
Q. Okay.
A. There might have been -- I'm -- between 2013/2014, I'm not -- I know I went back at some time in that time to do a teaching course for sales staff --
Q. Okay.
A. -- but I don't recall when.
Q. So it's possible it was in 2014?
A. It's possible. I just don't quite recall.
Q. And you don't keep records of any of that stuff?
A. No. Any payments that I receive from Johnson & Johnson went right to the corporation.
Q. Okay. What corporation?
A. That was Bellevue Obstetrics and Gynecology.
Q. Why did that company dissolve?

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A. Because I moved to Shenandoah and took a position with the hospital.
Q. Okay. Did you do anything in between those two jobs?
A. I worked -- I actually balanced two jobs there for a while, where I took a position at ICON Clinical Resources trying to learn how to do studies better.
Q. And did you practice medicine during that time?
A. Yes, I did.
Q. Okay. Where at?
A. Bellevue Obstetrics and Gynecology and my rural outreach clinics.
Q. And so Bellevue obstetrical was still open during the time you were at ICON?
A. Yes, it was.
Q. Okay. Did you have partners in that business?
A. No.
Q. Okay. You were a solo practitioner?
A. With a PA.
Or between 2001 and 2003 I had two partners.
Q. We just looked at your CV and it says you

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were a consultant for Ethicon from 2004 to 2014. Do you remember that?
A. Yes.
Q. In fact, you started consulting with them in 2002, didn't you?
A. I don't remember the exact time.
Q. Okay. Possible it was before 2004?
A. Yes.
Q. So you've never kept any of your billing records or payments you've received from Ethicon with your consulting agreements?
A. No.
Q. Okay. You got rid of all of those when you moved offices in 2013?
A. Yes.
Q. Do you keep any of your professional education or PowerPoints or presentations you've done for Ethicon?
A. I have kept -- I couldn't find a lot of them, and a lot of them were on a computer that was destroyed when I was traveling cross-country.
Q. Okay.
A. And so --
Q. When was that?
A. That was right around 2013, or so. It's

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one of those that I wish I would have taken the computer out or had a curbside -- or check it at the door. And it looked like someone had run over it; it was literally destroyed.
Q. So did you do a search for -- you said you found some of those presentations?
A. Yes. I --
Q. Are those on the thumb drive?
MR. SNELL: Paul, are those on -- are those on the thumb drive, Paul, or do you know?
MR. ROSENBLATT: No, they're not on the thumb drive.
MR. SNELL: Do we have them print out?
MR. ROSENBLATT: Yeah, I've got --
MR. SNELL: Tell him if you were able to find some of them.
THE WITNESS: A lot of them I just -- I know were on the computer that was destroyed.
MR. SNELL: No. He asked you which ones did you find.
BY MR. KUNTZ:
Q. Let me ask you this. The ones you found you forwarded to counsel?
A. Yes, I have.
Q. Okay. And --

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MR. KUNTZ: I just wanted to know if they existed.
MR. SNELL: Just let the record reflect we handed counsel a folder with numerous PowerPoint presentations inside there. All right.
MR. KUNTZ: I'll look at those later.
BY MR. KUNTZ:
Q. Have you ever -- how many clinical trials or studies have you participated in for Ethicon? We talked about the TVT Secur.
A. Secur. I believe with Ethicon that was the only one where I was a PI.
Q. Okay. Did you keep any of the documents from the TVT Secur study?
A. Yes. I would have to find where they're at, but yes.
Q. Okay. And can you provide those to defense counsel?
A. I would have to look through a lot of boxes, but I believe that I can provide that to counsel.
Q. Have you ever participated as an investigator for any other device companies related to pelvic floor products?
A. Yes. With Coloplast, with their Altis

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study, I was one of the sites for that, and that is the only one with pelvic organ prolapse. I also was an investigator in the late 1990s/early 2000s, I'm not sure exactly which time, on the vessel-sealing device for hysterectomy.
Q. Okay. What about any other SUI products that are non-Ethicon?
A. No.
Q. Do you currently have a consulting agreement with Coloplast?
A. Yes, I do.
Q. Okay. Any other device manufacturers?
A. AMS.
Q. Okay. Any drug manufacturers?
A. No.
Q. When did you first start working for AMS?
MR. SNELL: Form.
BY MR. KUNTZ:
Q. When did you start consulting for AMS?
A. I haven't done any paid consulting for them yet. I had a consulting agreement drawn up I believe it was August of this -- no, it would have been earlier than August. Sometime this year, in 2015.
Q. And what product were you going to consult with them on?

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A. It was just kind of a blanket consulting. That hasn't gone anywhere.
Q. Okay. Do you have a current consulting agreement with Coloplast?
A. I believe I do. I would have to find that, but I can -- I believe I could find it.
Q. When did you first start consulting with Coloplast?
A. I'm unsure.
Q. Why did you stop consulting with Ethicon in the last year?
A. They didn't offer any consulting agreements.
Q. Okay. Did you ask them why?
A. No.
Q. When did they first contact you to be an expert witness in this case?
A. I believe in July of this year.
Q. Who called you?
A. Paul Rosenblatt.
Q. So prior to your involvement in this case, you had been a consultant for Ethicon for at least ten years?
A. Yes.
Q. I'm going to -- let's mark your report as

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Exhibit 2.
(Exhibit No. 2 marked for identification.)
BY MR. KUNTZ:
Q. Doctor, this is just for the record. You can refer.
A. Okay.
Q. I'm just marking this --
MR. SNELL: That's okay.
BY MR. KUNTZ:
Q. -- to have it marked. You can use your copy of it.
This is your signature at the end of this report, correct?
A. Yes.
Q. Okay. Do you stand by all of the statements you made in this report?
A. Yes.
Q. Okay. Did you review this report yesterday in preparation for the deposition?
A. Yes.
Q. Anything you want to correct in the report?
A. I would have to go to one -- can I look through this a second?
Q. Sure.

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A. This is one that I found. This may take me -- I did not mark it in here, so it may take me a moment.
Q. Take your time.
A. This may take me a few moments. Do you want to --
Q. We'll do it on a lunch break, or something. We can do that.
A. I'll look through this because I'm trying to find it and I --
Q. Okay. But it sounds like there's something that you wanted to correct and you're going to look through it at a break --
A. Yes.
Q. -- and let me know?
A. Yes.
Q. Okay. How long did it take you to write this report?
A. That -- this was a chunk of that 100 hours.
Q. Okay. How many?
A. In writing this report, I would probably say 35 to 40 hours of that time, and I'm just taking a ballpark estimate.
Q. Okay.
A. That's just the writing and going over it.

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It's not the review.
Q. Did you prepare the Attachment C, the exhibit list? Actually, it might be B.
MR. ROSENBLATT: You're referring to the reliance list?
BY MR. KUNTZ:
Q. Yeah, the reliance list. I'm sorry.
A. Yeah, my reliance list.
Q. Is Exhibit -- strike that.
A. Yes.
Q. Did you prepare Exhibit B, the reliance list?
A. Yes.
Q. So you put this together?
A. This is a list of everything that I looked through and relied upon.
Q. Did you ask for any internal documents, or were they just provided to you by defense counsel?
A. Provided by the defense counsel.
Q. Okay. Did you ever ask for any deposition testimony of any Ethicon employees?
A. No.
Q. Okay. It's not important to you what some of the internal employees say about some of the issues of this lawsuit?

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A. I -- I have to look at the data that I was asked to look at, which was higher level.
Q. Okay.
A. And --
Q. So is testimony of the Ethicon employees not important to you in forming your opinions in this case?
A. No.
Q. Okay. You know David Robinson, right?
A. Yes, I do.
Q. You communicate with him -- or you did communicate with him a lot during your consulting days with Ethicon, correct?
A. Yes.
Q. Okay. It's not important to you what David Robinson said about the development or issues related to the TVT Retropubic?
A. No.
Q. Who put together the literature list in your reliance list?
A. This was my own. This was going looking at the various studies, doing the list.
Q. Okay.
A. And so if I were going through and found an article that referred to an article, then I would try

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to find that.
Q. Okay. Did you type this reliance list yourself?
A. No, I did not.
MR. SNELL: No. I will state, for the record, that is something that our paralegals typed.
BY MR. KUNTZ:
Q. Did you provide them with all of the articles that are on this list --
A. Yes.
Q. -- for the literature?
Okay. So did they provide you -- did defense counsel provide you with any articles?
A. Yes, they provided me with articles, and I provided them with other articles that I felt would support this.
Q. So this was -- this list was put together kind of jointly --
A. Yes.
Q. -- with respect to the literature?
A. Yes. It's a massive -- there's no way to get through all of that literature easily.
Q. So what kind of searches did you do for literature?
A. I did PubMed searches. I also looked at

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the systemic reviews, and then I would pull up articles they cited that I felt were relevant.

I tried to weed out as best I could on the level of data--it's just -- it's overwhelming when you have over 2,000 articles--and just try to create the levels within the pyramid of what I felt was a higher-level data.

Q. Did you read all 2,000 articles?

A. I skimmed through many articles. I can't say exactly how many.

Q. Okay. Ballpark guess?

A. Honestly, I don't have a whole lot of idea.

I then would go to the meta-analysis and then also the systemic reviews in order to be able to condense it down. I didn't want to repeat a lot of the work that had been done.

Q. All right. How many hours did you spend reviewing the internal documents that are cited on your reliance list?

A. I would probably -- this is, again, going to be a ballpark. Probably about ten hours.

Q. Okay. I also noticed that you reviewed several of the plaintiffs' expert reports.

A. Yes.

Q. Did you review those in detail?

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A. I reviewed over trying to get the gist of what they were saying, so -- on the expert reports, and then in the -- reading the depositions was more going through. I don't understand all of the legalese, and so --

Q. Okay. Did you -- did you review any of the exhibits to the depositions?

A. I don't recall -- no.

Q. How long did you spend reviewing the plaintiffs' expert reports that are listed on your reliance list?

A. I would say about an hour -- you know, on what they were saying, about an hour a piece. I would read them a lot like I would an article.

Q. Okay. Did you review all of the footnotes that are cited in the plaintiffs' expert reports?

A. No.

Q. Okay. You didn't pull those documents and look at them, did you?

A. No. Most of the documents were not related to -- they were hernia mesh. They weren't -- they weren't related to what I was asked to review.

Q. Okay. So you -- it's your testimony that most of the documents in the plaintiffs' expert reports related to hernia mesh?

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A. They were not -- I'm not -- part of theirs was related to hernia mesh, animal data, these kind of things. I was looking at some of the level of evidence and then looking at how they presented it.

Q. Okay. Did you -- so you didn't review any of the plaintiffs' experts' reliance materials that were attached to their reports, correct?

A. If it -- I shared many of the same documents that I had already reviewed.

Q. Okay. But if they were different ones that aren't on your reliance list and they're on the plaintiffs' expert reports, did you review those?

A. There were some that I did review, yes.

Q. Okay. Did you make a note of which ones you did and didn't review?

A. No, I did not.

Q. Okay. Were those printed out for you, all of the plaintiffs' documents that are on the plaintiffs' experts' reliance reports?

A. I reviewed over what the reference lists were, and then --

Q. Okay.

A. -- looked at -- there was overlap with what I had already reviewed, so --

Q. Okay. My -- that's not my question. So

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some of the documents on the plaintiffs' expert reports are the same as you have on your reliance list, right?

A. Yes.

Q. And there are different ones, as well, correct?

A. Yes.

Q. Did you review the actual documents?

A. As -- as in articles?

Q. Articles? Internal documents?

A. Many of the internal documents I did not pay credence to because it would not affect the evidence that I was asked to look at.

Q. So you didn't actually pull the documents or ask to be sent the documents in the plaintiffs' expert reports to review them, correct?

A. Correct.

Q. Okay. You just reviewed the reports and the body of the reports and not the documents cited or not the documents on the reliance list that were different than the ones you'd reviewed for your report --

MR. SNELL: Objection, form.

BY MR. KUNTZ:

Q. -- correct?

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A. What I did is if there was overlap -- there was such a huge amount of data there, so when it came to, say, internal documents, I -- or -- I didn't have access to e-mails or anything along this line, so on those, what I was doing is looking at level of evidence, so was this a randomized controlled study, was this in a systemic review, these kinds of things.
Q. Right. But you didn't look at the actual documents, correct?
A. Correct.
MR. SNELL: Objection, form.
BY MR. KUNTZ:
Q. Okay. And you didn't look at any of, say, the internal documents of Ethicon that are cited in the plaintiffs' expert reports, you didn't review those actual documents?
A. I did not feel that it would impact my viewpoint because I was relying on top-level data.
Q. So the answer to my question is, no, you did not review them?
A. If I did, it would have been very briefly as in a quick skim.
Q. Okay. All right. Who printed those documents off for you?
A. Those are received from plaintiffs'

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counsel -- or defense counsel.
Q. Okay. Were those on your thumb drive?
MR. SNELL: They should be.
MR. KUNTZ: Okay. So all -- so all of the plaintiffs' expert report reliance materials are on the thumb drive?
MR. SNELL: Yes. As far as I know, we sent him all -- every footnoted article or document or thing that was cited by your experts along with their reports; that should be on the thumb drive. If it's not --
Do you know if that's on the thumb drive?
MR. ROSENBLATT: I haven't checked. If it's not, we'll get that updated, but we'll send him a response.
MR. KUNTZ: Hold on. Did you provide them to him or not?
MR. SNELL: Yes.
THE WITNESS: Yes.
BY MR. KUNTZ:
Q. Okay. So every document that you reviewed in this case to give your opinions today is on that thumb drive?
A. Yes --
Q. Okay.

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A. -- the in-depth review. Some I skimmed, some I looked at more closely, yes.
Q. Okay. How long did you spend reviewing all of the documents that are cited in plaintiffs' expert reports?
A. I -- the thing is is that we have to look that a lot of the literature, you know, I've already reviewed because I've been reviewing it for 20-plus years.
Q. Let's break it down, internal documents. How long did you spend reviewing internal documents that were cited in plaintiffs' expert reports?
A. I'm unsure of an exact amount of time.
Q. Who's Nick Jewell?
A. I do not know.
Q. You don't know that name?
A. No.
Q. Did you review his expert report?
A. If I did, I -- I don't recall.
Q. Okay. Who is Howard Jordi?
A. I don't recognize that name.
Q. Who is Thomas Muehl?
A. I don't recognize that name.
Q. Did you read Dr. Margolis's expert report in the Carolyn Lewis case?

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A. No, I did not.
Q. Did you review any expert reports in the Carolyn Lewis case?
A. I'm not familiar with the Carolyn Lewis case.
Q. You never heard of the name Carolyn Lewis before today?
A. No.
Q. So if those expert reports are listed on your reliance list, is it fair to say that you did not review those?
A. Or I skimmed them very rapidly.
Q. Is it accurate to say that even if you did review any internal documents from plaintiffs' expert reports, they don't have any bearing on your opinions in this case?
A. That is correct.
Q. Why did you review the internal documents, then, that are on your reliance list?
A. As I say, if I looked at them, I listed them.
Q. Okay.
A. But there's a difference between looking at something in-depth versus going over. Also, I am very poor with names.

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Q. Is this the first time you've ever been asked by a medical device company to serve as an expert witness?
A. Yes.
Q. Have you ever been an expert in a medical malpractice case?
A. I have reviewed one case, but that was it.
Q. Okay. Have you ever been -- strike that.
Have you ever given depositions in the medical malpractice cases in which you were named as a defendant?
A. Yes.
Q. Okay. Did you give a deposition in Bunman v. Woods?
A. What was the name, again?
Q. Bunman, B-U-N-M-A-N?
A. I believe it was Putnam. I don't remember the name.
Q. Okay. What was the issue in that case?
A. It's been a long time ago. I -- I don't recall on many of the cases what it -- on that one, I don't have a recollection.
Q. Okay. What about -- did you give a deposition in Gardener (ph) v. Woods?
A. Yes.

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Q. Okay. What about Kutner (ph) v. Woods?
A. Yes.
Q. Gray v. Woods?
A. Yes.
Q. Okay. Hanson v. Woods?
A. Yes.
Q. Okay. What about Bremmer (ph) versus Woods?
A. I don't recall if I gave a deposition on that one. I don't recall.
Q. Is that -- was that a suit brought by the government; do you know?
A. I don't believe so.
Q. Was Bremmer represented by the U.S. Attorney's Office, do you know?
A. I don't recall.
Q. Okay. Do you -- did any of these medical malpractice cases involve issues related to stress urinary incontinence?
A. No.
Q. Okay. What about pelvic floor disorder?
A. There was one vesicovaginal fistula, but that was after a hysterectomy.
Q. Okay. Which was one was that?
A. I don't remember the name of the patient to

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be honest with you. It was 1994 is when it went to --
Q. Have you kept copies of any of these depositions?
A. No.
Q. Were you represented by the same person in all of these cases?
A. No.
Q. Have you ever been a party to any other lawsuits?
A. No, not that I recall.
Q. Have you ever had any contact with any other Ethicon -- strike that.
Do you know any of the other experts that have been named by Ethicon in this case?
A. Yes.
Q. Okay. Have you talked to them about this case?
A. Not at all.
Q. Okay. Do you know them?
A. Yes, I do.
Q. Okay. How do you know them?
A. Professionally, Denise Elser; and then Kim Kenton I know professionally and, also, she and I, on that Gore-Tex mesh, were coauthors.

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Q. Have you ever had any actions taken against your medical license?
A. No.
Q. Okay. Any Orders of Compliance?
A. Yes.
Q. Okay. What was that?
A. That was a case where I was at Jennie Edmundson Hospital and a patient of mine showed up at a hospital I did not have privileges. They tried to contact me and I was in the basement of the office. They were unable. I didn't have cell phone service. They transferred the patient to the University of Nebraska. The University of Nebraska had just switched from a Rolodex call schedule to computer, but they had not done it for the private physicians, and they were using old contact data.
Q. Okay.
A. That actually was from my residency several years before and they were unable to get ahold of me.
Q. Did the licensing department of Nebraska issue an order on that case?
A. They issued an Order of Compliance with no -- I want to say penalties, but that's not the right word. But I -- what I did is I cooperated and acknowledged they couldn't get ahold of me, and so

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there was no restrictions.
Q. When was that?
A. I think the incident happened in 2007 and that came out I believe in 2009, but I'm not exactly sure.
Q. Okay. Anything else?
A. No.
Q. Have you ever completed a fellowship in urogynecology?
A. No.
Q. Did you apply to fellowship programs?
A. No, I did not.
Q. Okay. Do you know now if you can become a urogynecologist without going through a fellowship?
A. After 2015, no, you cannot.
Q. And so you call yourself a urogynecologist because you passed what board?
A. I am board certified in both obstetrics and gynecology and female pelvic medicine and reconstructive surgery.
Q. When did you take that test?
A. 2013. It was the first year that it was available.
Q. Do you practice both in Nebraska and Iowa?
A. I now practice in Iowa. I have a license

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in Nebraska, but I no longer have hospital privileges in Nebraska.
Q. Do you bill for patients in Nebraska?
A. I have patients that come from Nebraska over to Iowa, yes.
Q. Okay. So you bill Nebraska Medicaid program?
A. Yes, I would say, because I can recall one patient that I have had that --
Q. Is your legal office in Nebraska or Iowa?
MR. SNELL: Objection, form.
THE WITNESS: My legal --
BY MR. KUNTZ:
Q. Is -- do you have an office in Nebraska any longer?
A. No, I do not.
Q. Okay. Do you have two separate companies or just one?
A. I don't have a company anymore. I'm employed.
Q. Okay. And you're an employee of?
A. Shenandoah Community Hospital.
Q. How long did you work at ICON Clinical Services?
A. Six months. At the end of November until

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May when they closed the office.
Q. Okay. So ICON -- where was ICON Clinical Services located?
A. Actually, right across over here (indicating), about 114th.
Q. And what were your duties there?
A. When I first went there, it was to become a primary investigator, but I was going through the training process. I actually wanted to learn how to do studies better, and it was the second largest Phase I company in the world, and approached them.
Q. Why did they close?
A. The corporate office in Dublin decided to close the office in Omaha.
Q. Okay. Why did you want to learn how to do studies better?
A. I felt that in my training, observational studies were about the best there was, and the level of data had changed during my evolution of my professional life, and I wanted to understand the business aspect but, also, really, how to do studies properly. I don't have the fellowship available to me, without having to quit my practice, and I thought that this would be one way where I could learn from the people that were doing the highest-level research

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for the federal government.
Q. Okay. Did you decide to -- after they closed down, to take up that endeavor any further?
A. No. I -- the opportunity arose in Shenandoah to align with exactly what I was looking for.
Q. Did you work on polypropylene mesh while you were at ICON?
A. No, I did not.
Q. Did you work on SUI products while you were there?
A. No, I did not.
Q. Did you work on TVT while you were there?
A. No, I did not.
Q. Did you work on any mesh products?
A. In research?
Q. Uh-huh.
A. No, I did not.
Q. I saw in your CV that you written an article with Linda Brubaker?
A. That was the -- the Kenton that I had mentioned earlier, Linda Brubaker was also on that.
Q. She was Dean at the medical school you were trained at, correct?
A. That is correct.

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Q. Okay. She's one of the most respected pelvic floor surgeons in the world?
A. I have a tremendous respect for Linda, yes.
Q. And do you agree that she has more experience and expertise in pelvic floor surgery than you?
MR. SNELL: I'm going to object, lacks foundation.
THE WITNESS: Linda and I share a lot in common.
BY MR. KUNTZ:
Q. Okay.
A. She has done much more research than I have, so she has --
Q. You agree she --
THE REPORTER: "She has" --
THE WITNESS: Done much more research and publication and education.
BY MR. KUNTZ:
Q. You would agree that she's an expert in mesh complications, correct?
A. I believe -- yes, I believe she is an expert in female pelvic floor disorders, yes.
Q. Are you doing any current research on polypropylene mesh?

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A. No, I have not.
Q. Okay. You've never written on polypropylene mesh, correct?
A. No, I have not.
Q. Okay. You've never lectured on polypropylene mesh outside of Ethicon, correct?
A. Yes, I have.
Q. Okay. Where at?
A. The Hong Kong Urogyn Association. I believe that was 2009. And the Taiwan Urogyn Association which I also believe was in 2009.
Q. Did Ethicon pay for you to go on those two trips?
A. No.
Q. Okay. You went on --
A. In 2009 I was invited by the Hong Kong Hospital Authority.
Q. Did Ethicon have any involvement in that trip to Hong Kong?
A. No, they did not.
Q. You received no payments from Ethicon for that trip?
A. Not -- I did receive payments for the Taiwan side of it but not for the Hong Kong side at all.

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Q. Was that the same trip?
A. Yes.
Q. Okay. Did Ethicon pay for your travel over there?
A. No, I paid for my travel.
Q. And Ethicon paid for what for the Taiwan part of the trip?
A. They -- in the Taiwan part of the trip, they paid for the hotel and my contracted amount. I don't remember what it was.
Q. Okay. Did they pay for any portion of your airfare?
A. No, they did not.
Q. Did they pay for your meals while you were over there?
A. Yes.
Q. Okay.
A. Actually, I am unsure.
Q. Okay. We'll go through it here in a little bit.
A. Yes, that I'm unsure because --
Q. So they did pay for part of your travel on your trip to Hong Kong and Taiwan, correct?
A. For the Taiwan portion.
Q. Any other lectures you've ever given,

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besides those two, on polypropylene mesh?
MR. SNELL: Form.
BY MR. KUNTZ:
Q. Strike that. Tell me every lecture you've ever given on polypropylene mesh. I thought I asked that, and you said Hong Kong and Taiwan.
A. No, that would be -- I'm just trying to go back and think. I think that would be correct.
Q. You've never written on the Burch procedure?
A. I'm going to -- I am going to go back in that I gave a lecture at University of Missouri, Kansas City, on the post FDA 2012 meeting on pelvic floor mesh. I believe I gave a grand rounds at --
Q. Ethicon paid for that trip?
A. No.
Q. Who invited you to that trip?
A. The chairman of the department, a perinatologist. I'm blanking on his name right now.
Q. Did you keep that presentation?
A. No, I don't have that presentation.
Q. Was that lost on the computer, too.
A. That was on my computer.
Q. What was that lecture about?
A. That was just reviewing pelvic floor mesh

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after the FDA meeting in September 2011.
Q. Okay. You never published anything on the Burch procedure, correct?
A. No.
Q. You never published or written anything on the pubovaginal slings?
A. No.
Q. You doing any research on polypropylene mesh right now?
A. No, I'm not.
Q. You're not an expert in chemical engineering?
A. No, I'm not an expert on chemical engineering.
Q. Not an expert in pathology?
MR. SNELL: Objection, form.
THE WITNESS: No.
BY MR. KUNTZ:
Q. Are you an expert in pathology?
A. No. I have taught histology in medical school and I have reviewed pathology slides with pathologists, but I am not a -- I am not a pathologist.
Q. Okay. When did you teach histology?
A. In my first year of medical school, I was a

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TA in the histology class.
Q. Where was that at?
A. Loyola-Stritch in Chicago.
Q. What book did you use?
A. I don't even recall.
Q. You're not an expert in polymer chemistry?
A. No.
Q. You've never done bench research on polypropylene?
A. No, I have not.
Q. Never done lab research on polypropylene?
A. No.
Q. Okay.
A. I've implanted a lot of it, but I haven't done research on it.
Q. Have you ever done any type of pathological analysis on explanted polypropylene mesh?
A. Just on what I took out, looked at, and sent to the pathologist.
Q. Okay. Have you ever looked under the microscope at explanted mesh?
A. I can recall one time where I was with a pathologist, yes.
Q. Okay. What was that?
A. That was a revision of a TVT that had

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obstructive symptoms.
Q. Okay. Why did you look at that mesh under the microscope?
A. I just wanted to. I asked the pathologist and I just wanted to look at it.
Q. You only wanted to do that one time with explanted mesh?
A. I didn't feel a strong need to continue looking. No, just the one time.
Q. Who was the pathologist?
A. I don't recall.
Q. When was this?
A. Several years. I couldn't give you a year to be honest with you.
Q. You're not a biomaterials expert?
A. I -- I -- as I say, I've implanted, but I would not consider -- call myself a biomaterials expert.
Q. You're not an expert on warnings?
A. Actually, I have been consulted on -- I've served on ACOG's Committee on Professional Liability; I was vice chair of that committee. I've also served on the ACOG's Quality and Patient Safety Committee and I'm presently on AUGS' Quality Committee.
Q. Okay. What do those institutions -- what

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do you do with warnings with those three groups?
A. Actually, looking on the safety design for, say, obstetrical units and these kind of things.
Q. Okay. What do you mean safety design? For the actual unit at the hospital?
A. Yes.
Q. Okay. So you work with warnings for, like, beds in hallways?
A. Well, what I do is looking at hospital design or team design for patient safety, is a better way to describe it.
Q. You're not an expert on warnings related to medical devices, correct?
A. No, I would not call myself an expert.
Q. Okay. I mean, you don't know what risk information a medical device company needs to put inside an IFU, do you?
MR. SNELL: Objection, form.
THE WITNESS: I believe that the FDA has very specific guidelines.
BY MR. KUNTZ:
Q. Okay. You don't know what those are as we sit here today?
A. No, I do not.
Q. Okay. You've never looked at them, have

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you?
A. Not the guidelines from the FDA, no.
Q. You've never drafted an IFU for a medical device?
A. No.
Q. You've never worked on warnings for a medical device?
A. Not that I recall, no.
Q. Okay. You have never worked on warnings for a prescription drug?
A. No.
Q. You're not a biomedical engineer?
A. No, I am not.
Q. You would agree you're not an expert on the design of medical devices?
MR. SNELL: Form.
THE WITNESS: I have worked on medical devices that have been patented, as a consultant.
BY MR. KUNTZ:
Q. Have you ever designed a medical device?
A. Actually, I worked on the design of the LigaSure Extend clamp for vaginal hysterectomy.
Q. Okay. Who manufactured that product?
A. Valleylab.
Q. What was your role in the design of that

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medical device?
A. Looking at the length of the clamp and what I felt would be effective for deep pelvises. Also, they consulted me on the development of the LigaSure Precise, which was a small clamp for ENT.
Q. Okay. Do you have a patent on medical devices?
A. No, I do not.
Q. When was this -- when was this device created?
A. The LigaSure Extend?
Q. Yes.
A. I don't know the exact date. It's been on the market for quite a while. It had to be the early 2000s.
Q. Okay.
A. It might -- might have been even the late 1990s, but somewhere in that category. The Precise, I'm not sure when it came out.
Q. What standards do manufacturers have to follow in designing medical devices?
A. That it -- they state that what it does is actually what it does, but beyond that, I don't have a tremendous amount of knowledge.
Q. Do you know what government standards they

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must abide by?
A. I know there are government standards. I do not know the exact ones.
Q. But you don't know the names of them?
A. No, I do not.
Q. Okay. Did you use any of those standards when you were designing this device or consulting with Valleylab?
A. I was more working with the engineers on that design.
And as I say, I'm definitely not an expert on federal regulations. That's one of the things, when I was at ICON, I was trying to understand that complexity.
Q. What are quality system regulations?
A. Again, I -- you're beyond my scope.
Q. What are current good manufacturing practice standards?
A. I am -- I'm trying to think back on what I went through at ICON because we had a section on that, but I don't recall it.
Q. Okay. When did you have this consulting agreement with Valley -- is it Valleylabs?
A. Valleylab.
I would have to look at when I did my

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study, and it was either late 1990s or early 2000s.
Q. Okay. So you ran a study for them after the product was designed?
A. No. I had done using another device that was shorter on a vaginal hysterectomy randomized study.
Q. Do you know what a company research is before a product is designed or released?
MR. SNELL: Form, vague, overbroad, incomplete hypothetical.
BY MR. KUNTZ:
Q. You can answer.
A. I have vague ideas, but I -- I have no solid regulatory aspect at all.
Q. Okay.
A. I'm usually asked, you know, such as with my work with Ethicon is, "What is your opinion on this?" I worked on a couple of the other -- the other, like with TVT Secur, and then looking at some of the evolution ones, but as in the regulation, that is something that's not what I would -- I've got other things to be worried about.
Q. You wouldn't consider yourself an expert in that area?
A. Pardon me?

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Q. You're not an expert in that area, correct?
MR. SNELL: Form, "that area."
THE WITNESS: I feel that I do not have the knowledge base. I may have a very vague knowledge base but not the level that would be required in manufacturing.
BY MR. KUNTZ:
Q. Tell me how a medical device company goes about designing a medical device.
MR. SNELL: Objection: Form, overbroad.
THE WITNESS: I feel that in the device they get an idea, and they do benchtop work, and then it evolves through; and I would say I'm more at the end of that process.
BY MR. KUNTZ:
Q. Okay. What experts are involved?
A. It would depend on what type of device.
Q. What about an SUI device?
A. I believe that with that you would have to have your mechanical engineers, you would have to have your safety individuals, you would have to have consulting with medical personnel, "Is this even a real option to be looking at?"
Q. What's a design history file?

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A. I -- again, I -- I would suspect, by that name, that it is the life -- the evolution of a device.
Q. Okay. Did you review the design history file for the TVT Retropubic?
A. I reviewed over -- I don't recall specifically on that. When Ulmsten was first coming out with this, with the integral theory, I found it to be a real challenge to my dogma, for one, but in looking at how he talked about using the various suburethral components, I did look at that.
Q. Okay. Do you know, one way or another, if you reviewed the design history file for the TVT, as we sit here right now?
A. I did not. I do not have a bundle that says that's what it is, no.
Q. Okay. Do you know what MedScan is?
A. I've heard of it. I'm not exactly -- I believe that is -- I will say it would be pure conjecture on --
Q. Do you know what Preventia is? Have you ever heard of Preventia?
A. No. Actually, I might have heard -- the name sounds, but...
Q. What's a failure modes and effects

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analysis?
A. I'm not sure.
Q. So safe to -- it's accurate to say you're not sure what the purpose of a failure modes and effects analysis is because you don't know what it is?
A. Correct.
Q. Do you know -- do you recall, as you sit here now, if you reviewed any of the failure modes and effects analysis involved in this case?
A. If I did, it would have been very briefly.
Q. Do you know if warnings for a product are part of the failure modes analysis?
A. If I don't know exactly what the failure modes analysis is, I can't say that.
Q. Do you know what a DDSA is?
A. That name rings a bell. I'm trying --
Q. So you don't know, as we sit here right now, or you don't recall?
A. Don't -- do not recall.
Q. What is ISO testing?
A. ISO testing is a standardized testing that is used -- it's International Standards -- I want to say Organization. I remember this some from my ICON days.

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And these are, I'm going to say, international standards so that way if a study is done in Croatia or the U.S., that they're using the same base knowledge, I believe.
Q. Did you review any of the ISO testing that was done on the TVT Retropubic?
MR. SNELL: Form, vague.
Go ahead.
THE WITNESS: If I did, it would have been briefly.
BY MR. KUNTZ:
Q. Do you believe that the TVT mesh can rope?
A. I have not seen it in my own hands, and I'm not aware in any Level 1 data that there's any clinical indication of that.
Q. Okay.
A. I believe if you were to stretch it in -- beyond its physiologic meaning, yes.
Q. What is the physiological range for the pelvic floor?
A. The -- 167 grams, I believe--I would have to pull up a chart--is -- I would have to find that chart. If I could look --
MR. KUNTZ: Yeah, let's take a quick break.

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(11:34 a.m. to 11:48 a.m. - Recess taken.)
BY MR. KUNTZ:
Q. When we were off the record, you were looking for a chart that discussed the physiological forces of the pelvic floor; is that correct, Doctor?
A. This comes from a lecture--and this is one of the ones from Gynecare at that time--where we looked at pull-out force comparison. This was in a human cadaver. The physiologic limit was 164 grams, and then we looked at the pull-out force.
And in -- one of the things that I also did in the TVT Abbrevo is I was one of the surgeons where they compared the pull-out force of TVT Secur to TVT Abbrevo and, actually, was there when they were doing the measurements of pulling the sling out of the tissues. And so when they talk about the physiologic limit, this is the assumption within the pelvis.
Q. Okay. I'm going to mark that as, I believe, Exhibit 3.
(Exhibit No. 3 marked for identification.)
MR. SNELL: Thank you.
BY MR. KUNTZ:
Q. What is the date of this -- strike that.

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Is this your presentation?
A. This was -- any presentation I did when I was speaking for Ethicon was approved by Ethicon.
Q. Okay.
A. I was allowed to have my own if it went through legal review --
THE REPORTER: "Have my own" --
THE WITNESS: My own slides if it went through legal review.
And so the only time that I would talk about my own experience, or anything, is if I made the qualifier, I'm now speaking not for Ethicon but as a physician -- pelvic floor physician doing the procedure.
BY MR. KUNTZ:
Q. So any presentation you gave for Ethicon had to be approved by them?
A. If I was -- if I was speaking for them, yes.
Q. Okay. Did you give this presentation for them?
A. Yes.
Q. Okay. When was this given?
A. Multiple times.
Q. Okay. And you refer specifically, on

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Page 7, to a bar graph talking about the pull-out forces of TVT-S and TVT, TVT-O?
A. Well, it was TVT Secur, both U and Hammock; Retropubic TVT; and then TVT-O.
Q. Does this talk about the in vivo physiological forces?
A. This was -- the 164 grams, I believe, was in the pelvis, and then this was how well it stayed in place at forces above that.
And so in this particular one, what we did is we implanted the device, and then they hooked up some machine that measured the force it took to dislodge it out of the tissues.
Q. So this, we're talking about pull-out forces as opposed to in vivo forces once the mesh is left in the body, correct?
A. I believe --
MR. SNELL: Objection: Form, asked and answered.
Go ahead.
THE WITNESS: I believe this 164 is the baseline --
BY MR. KUNTZ:
Q. Okay.
A. -- the physiologic.

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Q. Okay. And what's the basis for this study?
A. Specifically on this was looking at pull-out forces and that it exceeded physiologic forces.
Q. And where do we find that study, the results of that study?
A. That would probably be in some of the internal documents.
Q. Okay. Were those internal documents that are part of your reliance list?
A. I do not recall that this was part of the reliance list.
Q. Okay. Can you get us a copy of this study?
A. I think you would have to request it from the company. I don't think I would have access to it.
MR. KUNTZ: Can we get a copy to this study, Burt?
MR. SNELL: Let me see. You mean the actual cadaver study thing that they did?
MR. KUNTZ: Yes.
MR. SNELL: PSE 05-0396, Evaluation of the Pullout Force.
We'll check. I would think -- that may -- that's probably already been produced as part of

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the -- you know, that PSE number does seem -- I have seen that before. I think that has been produced.
BY MR. KUNTZ:
Q. When was this study done?
A. I do not know.
Q. Does this just relate to the force of the mesh during implant?
A. It's the physiological limit of the mesh.
Q. During implant?
A. I believe so. I am not positive.
Q. Okay. Does this test the force of the mesh when a patient is standing?
A. I -- I cannot say on that.
Q. Doctor, you were part of the study and presented on it. Was it or was it not?
A. I was not a part specifically of this study. I was a part of when TVT Abbrevo was coming out. They utilized me as the TVT Secur expert and then the placement of the TVT Abbrevo and then the pull-out forces out of the tissue.
Q. Okay. So forces of the mesh on pull out during the implant procedure, correct?
MR. SNELL: Objection, form.
THE WITNESS: No. This was where we put enough tension on it that we actually

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dislodged -- it was supraphysiologic to dislodge the mesh to see if the anchoring was the same.
BY MR. KUNTZ:
Q. Did you play any role in the TVT pull-out force study?
A. No.
Q. Okay. Have you ever seen the results of that study?
A. I probably have. I just don't recall specifically.
Q. Did it test the forces when the patient was lifting something?
A. No, this was a cadaver study.
Q. So not -- so it's a cadaver study so it couldn't be when the patient was lifting something, correct?
A. Correct.
Q. It couldn't have been when the patient was coughing, correct?
A. Correct.
Q. It couldn't have been when the patient was sneezing, correct?
A. Correct.
Q. It couldn't have been when the patient is running, correct?

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A. Correct, because it was a cadaver study.
And then I was involved in the development of the TVT Abbrevo. It was will the device stay in place; and, also, with Coloplast, I worked on a study in the design of the anchoring mechanism for the single-incision sling.
Q. Would you agree that the TVT was not designed to rope?
A. I -- I would agree that when the TVT is placed properly, I do not see any roping.
Q. Okay. Would you agree that when the TVT is placed appropriately it doesn't -- it wasn't designed to curl?
A. Curling would be a deformation, so that should not occur when placing following instructions for use.
Q. And when the TVT -- strike that.
Do you agree that the TVT was not designed to fray?
A. Actually, the edges -- it depends what you call fraying. I'm not sure -- when I hear fraying, I'm not sure exactly what that means.
Q. What does fraying mean to you?
A. Fraying means to me that if you stretch it, the edges start to change edges is what I would call

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fraying. There's other ways where you could sit back and look at a mechanically cut edge and say, Well, that edge is frayed because it's cut, it's not a sealed edge.
I really -- I don't hold credence to fraying. I don't honestly know what to think when they say fraying.
Q. Have you ever talked to anybody else at Ethicon about what they think the word fraying means?
A. I have talked to physicians that have said, Well, along the edges there could be some fraying because it's cut, and we cut mesh when -- if we are doing a sacrocolpopexy, we cut the mesh using a scissors to customize it, and they say, Well, the edges could fray on that.
Q. Have you ever seen any internal documents that suggest fraying of the mesh causes complications?
A. I have looked at documents where they talked about fraying and the potential, but I'm not aware of any quality studies. That would be very bottom-of-the-rung opinion. And when I was looking at this, it was what are the randomized controlled studies down to the cohort studies and these things. But when it comes to opinion, that's expert opinion

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and that's -- the level of evidence that I looked at was very low level.
Q. Do you know if Ethicon has ever done a study to see the difference in complications between laser cut mesh and mechanical cut mesh?
MR. SNELL: Objection: Form, foundation.
THE WITNESS: I believe that they have not done a study; however, when we look at our literature, so the laser cut mesh, which was utilized more in Europe, if we were looking at the evolution of studies that, say, start in 2008 to now, so they are five years, seven years out, that we're not showing an increased risk of complications or differences. And so my feeling is that that has been done just because we have studies that have followed that long enough.
MR. KUNTZ: And I'm going to move to strike after studies have not been done.
BY MR. KUNTZ:
Q. And ask again, Doctor: Has there ever been a study done by anybody comparing the complications of laser cut mesh to mechanical cut mesh?
MR. SNELL: Objection: Form, foundation.

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THE WITNESS: What we do is we have to take --
BY MR. KUNTZ:
Q. Doctor, answer the question: Yes or no?
MR. SNELL: Same objection.
BY MR. KUNTZ:
Q. Have you ever -- as you sit here today, have you ever seen a study comparing the difference in complications between laser cut mesh and mechanical cut mesh?
A. Yes, because you have randomized controlled studies that use both, follow the clinical complications, and showed no difference.
Q. Okay. Tell me what randomized clinical trial you have anywhere in your materials that tracks the difference between mechanical cut mesh and laser cut mesh.
A. It would be the assumption that if you have data that -- you had implants or -- you --
Q. Doctor, can you point to any study in all of these studies you have that distinguishes that mechanical cut mesh was used as opposed to laser cut mesh post 2007?
A. No.
Q. Okay. Do any of these studies show which one of the meshes was used in post 2007?
A. You have those incorporated into the studies that do not show any difference, so I have to take --
Q. But in any one of those studies does it say whether laser cut mesh is used or mechanical cut mesh is used?
A. Not that I'm aware of --
Q. Okay.
A. -- for Retropubic TVT.
Q. And you would agree that Ethicon still sells both products?
A. Yes.
Q. Okay. In any study -- and you can take as long as you want. In all of your studies you have post 2007, show me a study that distinguishes between mechanical cut mesh and laser cut mesh.
A. For Retropubic TVT?
Q. Yes.
A. Okay. Then what I would do is say that that was not in the study design that I'm aware of.
Q. Okay. Would you agree that the TVT mesh was not designed to shrink?
A. For Retropubic?
Q. Yes.

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A. There are studies that show that it does not appear to shrink, yes.
Q. Have you ever reviewed a study that shows that the mesh in the TVT Retropubic shrinks?
A. When you look at the Dietz study, it shows that it does not.
Q. That's not my question. Have you ever seen a study in your thorough review in studies you've been provided by defense counsel and studies you've gone out and looked at on your own, ever seen a study that says that the TVT mesh in the Retropubic shrinks?
A. I have not seen a quality study that reflects that.
Q. Okay. Have you seen any studies? In your report you say you've never seen one. Do you remember that?
A. I -- I do not recall any studies -- I recall studies that show it didn't. I don't recall studies that show that it did.
Q. Okay. So you've never been provided from defense counsel any studies that show that the TVT mesh shrinks?
MR. SNELL: Objection: Form, foundation.

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THE WITNESS: TVT Retropubic?
BY MR. KUNTZ:
Q. Yes.
A. I do not recall.
Q. Okay. Do you think that mesh in some of the other TVT devices shrinks? You keep saying -- you keep clarifying "Retropubic." Is there a TVT device where the mesh does shrink, in your mind?
A. Not that I'm aware of.
Q. Okay. Have you ever seen any internal documents from Ethicon that suggests that the Prolene mesh in the TVT Retropubic device shrinks?
A. No. And the literature would support that we are not seeing the long-term complications that would be associated with it, such as increasing urinary retention. It tends to be stable over time.
Q. What other -- are you aware of any -- well, you don't believe it shrinks so you don't know what complications it would cause, correct?
MR. SNELL: Form, misstates.
BY MR. KUNTZ:
Q. If the mesh did shrink, what complications would it cause?
A. If there -- and this is a hypothetical question, and so if -- what I would expect to see if

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there was shrinking would be increased outflow obstruction.
Q. Okay. When did you first start consulting with Ethicon, Doctor?
A. I believe you reported that it was 2002.
Q. And your CV says 2004, correct?
A. That is correct.
Q. Are you going to go back and change that?
A. If you -- I did not have all of my documents on that. I would be glad to change the CV.
Q. I'm going to hand you what's been marked Exhibit 4.
(Exhibit No. 4 marked for identification.)
BY MR. KUNTZ:
Q. Do you recognize that document?
A. My signature is on it, so yes.
Q. And that's a consulting agreement that you entered into in December of 2002, correct?
A. That is correct.
Q. And it's for the amount of $50,000, correct?
A. One moment here.
Q. The maximum amount of the contract was $50,000?

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A. That is correct.
Q. I'm going to hand you what's been marked Exhibit 5.
(Exhibit No. 5 marked for identification.)
MR. SNELL: Can I get a copy?
MR. KUNTZ: I'm sorry.
MR. SNELL: No. 4 or 5, you said?
MR. KUNTZ: 5.
MR. SNELL: 4 was prof. ed. slides?
MR. KUNTZ: 4 was 2002.
MR. ROSENBLATT: 3 was the prof. ed. slides.
MR. KUNTZ: 4 was the 2002 contract.
MR. SNELL: Can I get a copy of that?
MR. KUNTZ: It's not on the thumb drive?
MR. SNELL: I don't know.
BY MR. KUNTZ:
Q. What is this document, Doctor?
A. Could I ask a question? How do I update the CV to reflect 2002?
MR. SNELL: Don't worry about that.
THE WITNESS: Okay.
MR. SNELL: This is a deposition where

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you answer his questions to the best of your ability.
THE WITNESS: Okay.
MR. SNELL: You don't need to be worried about updating stuff.
BY MR. KUNTZ:
Q. I promise you at trial we will not cross-examine you about your CV, about that.
MR. SNELL: I hope you do.
So this is Exhibit 5.
BY MR. KUNTZ:
Q. Do you recognize that document?
A. Yes.
Q. And the maximum --
A. I recognize my signature, anyway.
Q. Right. That's your signature at the bottom of this.
A. Yes.
Q. And the maximum amount of this contract was $25,000, correct?
A. That's correct.
Q. Did you have a consulting agreement for 2004?
A. I believe so.
Q. Okay. You can't find that one. Do you know what that amount was for?

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A. No idea. It was the maximum amount. Whether I got paid that or not, I have no idea.
Q. So some of these years you didn't get paid the maximum amount; I assume that's your testimony?
A. I would assume in some of those cases. In most of the early years, I was actually working with the Thermachoice device and not the uro/gyn device.
Q. Do you keep track of how many payments you received from Ethicon?
A. I -- as I say, my office manager opened the mail. I didn't have much contact with that at all.
Q. Did you keep any of those records?
A. Most of those have -- the oldest ones I -- wouldn't be there. I might have --
Q. What years do you have?
A. I don't know specifically with this. It would be the accounting of the office. That was all handled by my office manager.
Q. Okay. Do you have any idea what years you would have?
A. No.
Q. 2010?
A. I would have to look and see. I -- we should go back about seven years, I would say.
Q. Okay. So you keep the records going back

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seven years?
A. They're kept off-site, so -- and after seven years, they're destroyed.
Q. Okay. But you can get the ones for the past seven years, correct?
A. I'm not sure I would have the individual receipts or just a summation; I'm not sure.
Q. But, at the very least, you have a summation?
A. The accountant does, yes.
Q. But you did have a consulting agreement for 2004?
A. Yes, I believe I had a consistent consulting up to date from, I guess, 2002 up to whenever the last one was, which I'm unsure of.
Q. Okay. You think it was two thousand -- the end of 2013?
A. That would be my best guess, but I'm...
Q. Okay. I'm going to hand you what we've marked as Exhibit 6.
(Exhibit No. 6 marked for identification.)
BY MR. KUNTZ:
Q. Is that your signature at the end?
A. I'm flipping back to that. Yes -- well,

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yeah, it looks like it. It's a little bit poorly copied, but yes.
Q. And you'd agree the maximum amount available on this contract was $100,000?
A. That's correct.
Q. Did you have a consulting agreement for -- well, again, you've had one every year from 2002 --
A. I believe so, yes.
Q. -- up to 2013?
I'm going to hand you what has been marked as Exhibit 7.
(Exhibit No. 7 marked for identification.)
BY MR. KUNTZ:
Q. Is that your signature at the end?
A. I'm looking for one. Yes.
Q. And this maximum contract amount is 33,000, correct?
A. Yes.
Q. Let me hand you what's been marked Exhibit 8.
(Exhibit No. 8 marked for identification.)
THE WITNESS: Yes.
MR. SNELL: Can I get a copy of that?

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MR. KUNTZ: Uh-huh.
MR. SNELL: Thank you.
BY MR. KUNTZ:
Q. Is that your signature?
A. Yes, it is.
Q. Okay. Is the maximum amount $30,000 under that contract?
A. That is correct.
Q. Okay. Do you know if you exceeded your contract amount of $30,000 in 2010?
A. The answer is that all went to my office manager. I pretty much didn't pay attention.
Q. Okay. So you have no idea, as you sit here today, any of the amounts you've been paid from Ethicon?
A. No, I don't. I really don't. They --
Q. But you do keep summations of the last seven years in storage?
A. I -- I believe that they should be available, yes.
Q. Do you know if you signed a second contract in 2010?
A. I don't recall.
Q. Okay. Would you disagree that you made over $135,000 from Ethicon in 2010?

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MR. SNELL: Objection, foundation.
THE WITNESS: I wouldn't disagree if you have the numbers.
BY MR. KUNTZ:
Q. And you signed a contract in 2011, correct?
A. I believe so.
Q. I'm going to hand you what is No. 9.
(Exhibit No. 9 marked for identification.)
BY MR. KUNTZ:
Q. Is this a second contract for 2010?
MR. SNELL: Objection: Form, lacks foundation.
THE WITNESS: Yes. It says will cover 11/23/2010.
BY MR. KUNTZ:
Q. Okay. And you signed this in 2010?
A. I signed this -- I'm not sure if it's 11/19 or 11/17/2010, yes.
Q. What's the maximum amount on that contract?
A. $75,000.
MR. SNELL: You're allowed to look at the document to answer his questions, okay?
BY MR. KUNTZ:
Q. Doctor, I'm going to go through several

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cities and tell me if you've attended an Ethicon event in that city.
Denver?
A. I -- yes.
Q. Okay. Phoenix?
A. Yes.
Q. Chicago?
A. Yes.
Q. San Francisco?
A. Yes.
Q. Las Vegas?
A. Yes.
Q. Irvine, California?
A. Yes.
Q. St. Petersburg, Florida?
A. Yes.
Q. Sonoma, California?
A. Yes.
Q. Is that a wine dinner?
A. I'm not sure if -- I'm -- I did an extensive amount of traveling for Ethicon. I wouldn't be able to tell you specific dates.
Q. And that extensive amount of travel you've done has all been paid for by Ethicon, correct?
MR. SNELL: Lacks foundation, form.

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BY MR. KUNTZ:
Q. Did they pay for your travel expenses in all of these trips?
A. They did pay for travel expenses, yes.
Q. Did they pay for your time?
A. They paid for my time, yes.
Unfortunately, when I did these lectures or labs, I had a business to run, and in many times, actually, I lost money working and lecturing.
Q. Okay. Do you know how many days in 2010 you worked for Ethicon?
A. There were some times where I would set aside two days a week, especially when we were doing the Thermachoice early on, where I would free that time up to go around the country, yes.
Q. What year was that or years?
A. Working with Thermachoice -- and that's probably more when it went back to 2002, because I worked extensively with Ethicon and national organizations on bringing that procedure into the office and then, also, worked on the economics of it, et cetera. It's -- it took a huge amount of energy. It was something I was very passionate about.
Q. So some time period you spent two days a week consulting for Ethicon?

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A. Probably in 2002 -- or somewhere '3, '5, somewhere in there; I would try to set aside two days a week, and then I opened my practice up on weekends and evenings when I was there in order to make up for the loss.
Q. So two days a week during those time frames is over a hundred days a year?
A. I wouldn't say -- on some weeks I would set aside two days. It would depend -- we had a huge coordinating effort. There was five of us nationwide that were doing a lot of the lectures on Thermachoice.
Financially it was very difficult.
Q. Same -- or Sonoma, California, you've been to?
A. Yes.
Q. Ethicon paid for that travel?
A. Yes.
Q. Salt Lake City?
A. Yes.
Q. Ethicon paid for that travel? "Yes"?
A. Yes.
Q. Dayton, Ohio?
A. Yes.
Q. Baltimore, Maryland?

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A. Yes.
Q. San Diego, California?
A. Yes.
Q. Orlando, Florida?
A. If it's on that list, ab- -- you know.
MR. SNELL: Just answer his questions, okay?
THE WITNESS: I --
MR. SNELL: Let me tell you. You're not here to assume things. You're here to answer his questions. That's it. Okay?
THE WITNESS: Orlando I don't specifically recall, but I will say yes.
BY MR. KUNTZ:
Q. Dallas, Texas?
A. Yes.
Q. Kansas City?
A. Yes.
Q. Barcelona?
A. I did lecture in Barcelona, yes.
Q. Where else did you go in Europe for Thermachoice?
A. Also London. I was brought in for an expert round table.
Q. Do you know what cities you've been to

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specifically to promote pelvic floor products, SUI and POP?
A. I didn't do as much -- much --
MR. SNELL: Hold on, I'm sorry. I'm sorry. I missed -- I just saw the question. Objection, form.
THE WITNESS: I don't -- I don't recall the exact cities. I did a lot of cadaver training. And exact lectures, I don't recall. I believe one that comes to mind was in southern California. I'm not sure what city.
BY MR. KUNTZ:
Q. Okay. And you were paid for all of these cadaver labs, correct?
A. Correct.
Q. Okay. And you were paid for all of these training courses?
A. Yes.
Q. Okay. And your expenses were paid?
A. Yes.
Q. You've promoted TVT Retropubic?
A. Yes.
MR. SNELL: Objection, form.
BY MR. KUNTZ:
Q. TVT-O?

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MR. SNELL: Same objection, to the extent you're using "promote." That's a running objection.
THE WITNESS: I lectured --
THE REPORTER: What was the last part on the objection?
MR. SNELL: That's a running objection to the extent the word "promote" is in it.
BY MR. KUNTZ:
Q. Do you consider yourself out there promoting Ethicon products?
A. I looked at it as I was educating physicians --
Q. Okay.
A. -- on the use of the device and, also, that if they were doing Retropubic slings, that this may be something that they could consider into their own armamentarium.
Q. So you educated physicians about TVT Retropubic?
A. Yes.
Q. The TVT Obturator?
A. Yes.
Q. The Prosima?
A. Yes.

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Q. The Prolift+M?
A. Yes.
Q. The Prolift?
A. Yes.
Q. Thermachoice?
A. Yes.
Q. What other Ethicon products?
A. TVT Secur.
Q. Any other products from Ethicon or Johnson & Johnson?
A. No, not that I recall.
Q. Did any of Ethicon's sales staff ever travel with you to any of these meetings?
A. I -- they might be there, yes. And then --
Q. So Ethicon would have sales reps at a lot of these meetings you attended?
A. Yes.
Q. Do you know Ethicon calls you one of their key surgeons; did you know that?
A. I was aware of that, yes.
Q. Would you agree you were a big advocate for Prosima?
MR. SNELL: Form, foundation.
THE WITNESS: I think I was a big advocate for pelvic floor reconstruction and the

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treatment of incontinence, along with Thermachoice.
BY MR. KUNTZ:
Q. When you were out educating these surgeons at these events, did you ever talk about any other products besides Ethicon products?
A. Yes.
Q. Okay. What products would you talk about?
A. Well, when I would do -- especially with Thermachoice, I had the other technologies available. I, also -- with the Essure device, there was a couple times where that was co-promoted.
Q. Did you work on the Essure device?
A. I actually was a consultant for them in some of their Phase -- in the developing from Phase I to II, yes.
Q. Is that still on the market?
A. Yes, it is.
Q. Do you think it's still within the standard of care to place the TVT Secur?
A. It is now off the market, and if I had it available in my hands, I had good results. The unfortunate thing was that it was intersurgeon variance, and that was one of the more frustrating things I had with it is that it's a nuance procedure and if you didn't understand the nuance, you didn't

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get the good results.
Q. So you attended company-sponsored speaker programs for Ethicon, correct?
A. Yes.
Q. You spoken at -- you spoken -- strike that.
Have you ever spoken for Ethicon in any professional society meetings?
A. Yes, with the disclaimer that I was a consultant with Ethicon.
Q. Which ones?
A. There's AAGL, I know. I'm sure there's probably one of the annual clinical meetings at ACOG. There's many -- there's more than that. I just don't recall.
Q. Okay. And would Ethicon pay your travel to attend these society meetings?
A. Sometimes they would. Sometimes, if I was going to the society meeting, then I would pay my own.
Q. Okay. Would you be in Ethicon's booth at these society meetings?
A. I have been at Ethicon's booth in society meetings. In fact, I did a live tele-surgery once.
Q. You've attended Ethicon or run preceptorships and surgical training for their

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products?
A. Yes, I have.
Q. You've been at company sales training presentations?
A. Yes.
Q. You've been on advisory boards --
A. Yes.
Q. -- for Ethicon?
Have you ever told Ethicon you could not work on one of their products?
A. I told Ethicon, if I had an ethical problem with anything, I would not work on it.
Q. Okay. Has that ever occurred?
A. Not that I can recall.
Q. Have you ever told Ethicon that you felt like one of its products was not safe?
A. No. I do not recall.
Q. Have you ever told Ethicon that they should not market one of their products?
A. I do not recall.
Q. Do you disclose your relationship with Ethicon to your patients prior to implanting the --
A. Yes.
Q. -- hold on, to implanting one of their products?

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A. Absolutely.
Q. Do you put that in your written consent?
A. No. I inform the patients that -- well, not with Ethicon, but I actually tell them even today, "I served as a consultant with this company. I no longer have any financial ties." But I disclose that to my patients on anything I recommend.
Q. Do you think inventors should be allowed to participate in studies attempting to establish the safety of the device or product they invented?
A. I believe that if they have done the studies, are doing the studies with the idea that they can be replicated, yes, but I would not have much validity in somebody that does a study with their device that has not been replicated by others. I would not, in good conscience, be able to look at that and tell the studies were done.
Q. You've read many studies that you reviewed that the author state in the conflict of interest section that they have some relationship with Ethicon?
A. Yes.
Q. Okay. Have you ever asked to see their consulting agreements?
A. No.

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Q. Have you ever asked how much money any of those physicians have been paid by Ethicon?
A. No.
Q. Have you reviewed any of the contracts between Ulmsten and MedScan Ethicon related to his purchasing agreement.
A. The only one that I recall was for a sum of $400,000 if the study -- multi-center study reflected his data. That's the only one I recall.
Q. That's the only contract you've reviewed?
A. Would that be considered -- I guess it would be considered a contract.
Q. But if you reviewed it, it's on your reliance list?
A. Yes.
Q. Do you know AMS refers to you as a huge J&J supporter?
A. No.
Q. Does that surprise you?
A loyal customer; does that surprise you?
A. Wouldn't surprise me.
MR. SNELL: Objection -- objection, foundation on "surprise."
BY MR. KUNTZ:
Q. Surprised that the AMS refers to you as a

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partner of Ethicon?
MR. SNELL: Same objection, relevance.
THE WITNESS: I guess what I would say is AMS has approached me to be a consultant, so I'm not aware -- I don't --
BY MR. KUNTZ:
Q. Do you feel like you're a partner with Ethicon or --
A. Especially --
Q. -- or were?
A. -- with Thermachoice, absolutely.
Q. What about with their SUI products?
A. I felt more as an educator.
Q. Would you agree at various times over the past years you were Ethicon's highest volume user of its products in the state of Nebraska? Do you know that one way or another?
A. I do not know that, but it would not surprise me.
Q. Do you know a single doctor in Nebraska that's implanted more Ethicon products than you?
A. I haven't personally asked anyone, so I'm not aware of anyone.
Q. What about in Iowa?
A. I haven't asked anyone. I -- that would be

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more internal documents I'm not privy to.
Q. How many times have you visited Ethicon's headquarters?
A. I'm unsure.
Q. Five?
A. More than five.
Q. 15?
A. Over the years, I would -- and I am just -- this is a plain guess.
MR. SNELL: Well, you're not here to guess, right? You're here to give testimony truthfully under oath. You can give him -- what do you call it, an estimate that's reasonable --
MR. KUNTZ: Estimate.
MR. SNELL: -- but don't guess. He doesn't want you to guess and I don't want you to guess. Okay?
THE WITNESS: Honestly, I don't know. More than ten. That's probably the best I could do. I just have no idea.
BY MR. KUNTZ:
Q. All right. How many times have you visited the AMS headquarters?
A. I believe three times.
Q. Okay. How many times have you visited

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Coloplast headquarters?
A. Probably four times.
Q. Where is AMS headquarters?
A. Both of them are in Minneapolis.
MR. KUNTZ: This might be a good breaking point.
(12:29 p.m. to 1:31 p.m. - Recess taken.)
BY MR. KUNTZ:
Q. Okay. We're back after lunch break, Doctor. Is there anything you want to add to your testimony from earlier this morning, or change?
A. I would like to clarify on when I would go lecture for Johnson & Johnson, that I was not paid door to door. It would only be for the time that I lectured, so if I spent a day getting someplace, I was not compensated for that time.
Q. Thank you.
Anything else?
A. I --
Q. Oh, I'm sorry. I had asked you before the break to look through your report, to see if there were any changes; you would look over at lunch. Why don't you go ahead and tell me the correction or addition you wanted to add.

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A. What page was that? I didn't take this with me.
Q. Let's go off the record.
(Discussion off the record.)
MR. KUNTZ: Okay. We're back on the record now.
BY MR. KUNTZ:
Q. Doctor, you had a change in your report or just an editorial error, I guess, or addition. Will you tell us what you changed.
A. What the sentence had stated priorly was (Reading):
By contrast, surgeons performing autologous fascial slings would utilize a 1 centimeter tube knitted Dacron buttress with a Stamey procedure with a 1 centimeter tube of knitted Dacron arteriography to help prevent the suture from tearing through the tissues.
My correction is:
By contrast, surgeons performing Stamey procedure would utilize a 1 centimeter tube of knitted Dacron arteriography to keep -- to help prevent the suture from tearing through the tissues.
Q. Thanks.
Can you tell me a little bit about your

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current practice, what you do week to week.
A. My current practice is I am a urogynecologist at Shenandoah Medical Center. I also do some general gynecology. I would say about 85 percent of what I do is urogynecology, 15 percent gynecology; however, when my partner is out of town, I will take call for obstetrics.
Q. Okay. What type of surgeries do you perform?
A. I perform native tissue vaginal repairs, I perform various types of sling procedures, I perform laparoscopy, though my special interest is vaginal surgery, and I also do perform blocks for pelvic pain.
Q. Okay. Do you perform pubovaginal slings?
A. I have performed one in the last five years.
Q. What were those circumstances?
A. It was in a patient that did not want to have mesh implanted.
Q. Ever perform a Burch procedure? Strike that.
When is the last time you performed the Burch procedure?
A. I do not recall performing a Burch in the

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last five years.
Q. How many laparoscopic Burches did you perform in your career?
A. I would say 50 to 100 as an estimate.
Q. And you were doing those in the early '90s?
A. The laparoscopic Burches were more in the later '90s.
Q. You agree, when you stated in your report, that the success rate with Burch is 70 to 80 percent, correct?
A. I'm -- in my report, I do state in there, but, also, in longitudinal studies it has been shown to decrease over time.
Q. What's the success rate for the TVT?
A. It would depend on how you determine success.
Q. Okay. What about for recurrence? I'm sorry. What about for incontinence? I mean --
A. The goal with success would be, from my perspective, patient satisfaction, is your life improved.
When I look at the literature, what I want to look at is does it last long term, are the complications acceptable. We are now doing -- asking validated questionnaires of patients, which is

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something that I'm just starting to do. Also, assessing is the quality of life or when I see them for their immediate post-op check, which is usually at about four weeks, I'm assessing: Is the tissue healed, is it tender, are they happy with the results, making sure that they're not in retention, and I always ask them, "Is your life better?"
Q. Okay. And what -- from a patient satisfaction standpoint, what is the success rate for TVT?
A. In my own hands, it's probably about 95, 96 percent.
Q. What about in the literature?
A. The literature is variable but in the upper 80s to low 90s.
Q. Have you seen studies that put it below?
A. Yes, there are studies out there, but when you look at the randomized controlled studies or the meta-analysis or such Cochrane reviews or such as the SGS, they're in the 80 range.
Q. Do you use any synthetic mesh for prolapse repair?
A. I do for sacrocolpopexy, and recently I did have a patient that I used a vaginal approach, that I cut because there was a very large defect on one side

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so I hand cut the mesh for a paravaginal repair.
Q. Aside from that one patient, you don't use synthetic mesh transvaginally to perform organ prolapse repairs, correct?
A. I do not feel that I have done enough lately, and because I was what I would call an expert on Prolift and is no longer on the market, I have waited to see with the other kits, but I have not -- I do not feel that I have enough adequate training at this point to proceed with implanting them, because I'm not trained specifically on that implant device. And I feel very strongly that you -- physicians, if they're going to be implanting, need to be trained specifically on the nuances of that device.
Q. Do you treat patients for complications related to slings?
A. Yes.
Q. Okay. Do you treat patients for complications related to the TVT Retropubic?
A. Yes.
Q. What are the type of complications you treat for TVT Retropubic?
A. It would be mesh erosions into the vagina and urinary retention would be the big two that I would see, and that's still in a minority of

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patients.
Q. What about chronic pain?
A. With chronic pain, what I do is I evaluate very certain areas --
Q. And hold on, before you explain it, do you treat patients for chronic pain related to the TVT Retropubic device?
A. I have treated one patient and in all of my time directly related to TVT.
Q. Was that your own patient?
A. No, it was not. That was actually referred in by the urologist that performed it.
Q. Okay. What about dyspareunia.
A. I really don't see dyspareunia with this. I see lots of patients with dyspareunia, but when I have a patient that has had a Retropubic sling, whether I placed it or anybody else, what I do is I try to elicit exactly the dyspareunia. So in the history, is it on deep penetration, is it on penetration, where is it located; and then I actually map out in the pelvis where the pain is located.
Q. Have you ever done any revisions on TVT Retropubic --
A. Yes.
Q. -- products?

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A. Yes.
Q. Okay. How many?
A. I would say my reoperation rate is right around 3 percent, so --
Q. Is that for your own patients?
A. Yes.
Q. Okay. What about --
A. 2 to 3 percent, yes.
Q. How many revisions have you done on patients that weren't your own patients?
A. I would be taking a guess. Over the last, say, ten years or so, around 100. That wouldn't just be TVT, though. That would be any suburethral mesh, whether it was TVT or Sparc. I -- I don't really break that all down.
Q. So for your -- I want to make sure this is clear. For your patients, with the TVT Retropubic is a 3 percent reoperation rate?
A. Yes, I would say.
Q. And in total, all midurethral slings combined you've performed approximately 100 revision surgeries; is that accurate?
A. That -- I think we would have to go back and read the question, again, because I think it was referred -- or patients that I did not operate on.

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Can you --
Q. Okay. Let me see if I can clean this up. How many -- approximately how many revision surgeries have you done on slings of any type, in total?
A. I would say -- because lately I haven't being seeing that many, anywhere between five and ten a year I believe would be a reasonable estimate.
Q. Okay. Since two --
A. I'm just going to say, the last ten years.
Q. Now, your reoperation rate for just TVT Retropubic is 3 percent?
A. 2 to 3 percent. I would -- usually that would either be a mesh erosion -- I presented a abstract on the treatment of mesh erosions with laser. I don't remember the breakdown of the patients on that.
Q. So did you --
A. Or ureterolysis, so simple procedures.
Q. Did you -- and I think you told me you put in approximately 2,000 Retropubic slings?
A. Somewhere in there.
Q. And that was Retropubic slings?
A. Well, I would modify that and say 2,000-plus slings, yes.
Q. The whole universe of slings?

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A. Right.
Q. You don't keep track of that number?
A. Not --
MR. SNELL: Objection, form.
THE WITNESS: -- anymore.
BY MR. KUNTZ:
Q. Okay. How did you come up with your reoperation rate being 3 percent?
MR. SNELL: Objection, misstates. He said 2 to 3 percent.
BY MR. KUNTZ:
Q. Okay. How did you come up with your reoperation rate being 2 to 3 percent?
A. When I would have a patient come on back and they would either have a voiding dysfunction or urethral -- or not a urethral, a vaginal erosion--I haven't had a urethral erosion yet--then I would sit back and have a good guesstimate of how many I done because I do them very often.
And then I would sit back and say this would be -- this is how many I've done this year, this is how many I've implanted this year.
Q. Okay. And so did you keep track of how many you implanted each year?
A. I kept a running track in my mind.

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Q. So this is a mental list?
A. Yes.
Q. So you don't have any list anywhere where you have exact numbers written down on a spreadsheet or piece of paper --
A. No.
Q. -- for the amount you've implanted?
A. No.
Q. Okay. For the amount you've done reoperations on?
A. No.
Q. Okay.
A. I mean, there would probably be some billing records, or something, somewhere where we could look, but...
Q. So you could maybe find that number if you looked for it?
A. Actually, I'm no longer using that billing service and so I'm not sure I could find it using the billing.
Q. And does that go for your erosion rate, too; that's a guesstimate, that's not something you keep hard numbers on?
A. No, I don't keep hard numbers on.
Q. Okay. So you don't keep hard numbers on

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the type of operations you do, correct?
MR. SNELL: Objection, misstates.
THE WITNESS: Correct.
MR. SNELL: Did you say types?
MR. KUNTZ: Yeah.
MR. SNELL: That's a misstatement. Object, form.
BY MR. KUNTZ:
Q. Do you keep numbers anywhere besides your head of any operations you do?
A. Yes.
Q. Where?
A. They would be in billing records and things, but I don't have those available to me.
Q. Can you get those?
A. I do not know if I can get those.
Q. Okay. And when you looked and you put numbers in your expert report of 1 percent erosion rate, 2 to 3 reoperation rate, that's all coming from your head, correct?
A. My data closely reflects the data that's out there, yes.
Q. That wasn't my question. All of those numbers in your report came from your mental estimates as opposed to looking at any hard data or

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numbers to make those determinations; is that accurate?
A. I would say that that is reasonably accurate.
Q. Have you ever removed or revised mesh because of pain?
A. I talked about the one earlier where this was a urologist that sent a patient in that had an ilioinguinal nerve pain that responded to a block. And then I excised that part above the fascia.
Q. Do you believe TVT Exact is the gold standard?
A. I do not believe that the randomized control studies are going to suggest a gold standard for anything but Retropubic, whether it's TVT or TVT Exact.
Q. Okay. Do you think the mechanical cut mesh is the gold standard or the laser cut mesh?
A. I believe that the data shows in the long term that mechanical cut was the gold standard. But the change, and as we've talked about earlier, is do the studies delineate whether it's laser cut or mechanically cut, and that I -- that I cannot expound upon.
Q. Is the AMS MiniArc the gold standard?

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A. I feel that the AMS MiniArc is an alternative, but it is not -- long-term studies are not there, so I cannot assess that.
Q. What about the TVT Abbrevo; is that the gold standard?
A. Again, the -- when I have to look at what I was asked to do evaluating Retropubic TVT and, specifically, mechanically cut, the data on that and in some of the authors have said that it is the gold standard.
Q. Have you ever done a survey of any physicians to determine what they believe is the gold standard --
A. No, I have not.
Q. -- yourself?
Do you believe that the AUGS physician statement applies to all slings across the board?
A. I think that when AUGS and SUFU came together, they reviewed the meta-analysis data and that applied most of the RCTs, the higher Level 1s, are Retropubic TVT.
Q. Do you agree that the AUGS statement says that the data is only good for up to one year?
A. They were -- let me have the AUGS statement so I can make sure I'm not misquoting, please. This

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may take me a second, too.
MR. SNELL: That's fine.
Do you have a copy of it handy?
MR. KUNTZ: No, I don't, no. I thought you kept one in your briefcase.
MR. SNELL: There are so many good position statements.
(Discussion off the record.)
THE WITNESS: I thought I had it in this pile.
BY MR. KUNTZ:
Q. I thought I saw it in there, too. We can get a copy of it.
A. AUGS Position Statement on Mesh Midurethral Slings for Stress Incontinence -- is this the one?
And what did you want --
Q. Let me see this.
A. -- because there's a lot to...
Q. Do you agree with this statement, Doctor: That the safety and effectiveness of multi-incision slings is well established in clinical trials that follow patients for up to one year?
A. That's one part of the document.
Q. Uh-huh.
A. How --

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Q. Do you agree or disagree with that statement?
A. That that is in this document, but that is just one part of the document.
Q. Do you agree with that statement or disagree with that statement?
A. That was the FDA statement. That wasn't the AUGS statement. It was included in the AUGS part.
Q. Why was it included in the AUGS statement?
A. Because when they were doing this, they had -- this was one part and this is -- they wanted to include that the FDA had looked at that.
Q. Okay. So do you agree or disagree with that statement by the FDA?
A. I -- on the FDA website, I agree that the FDA felt that the safety and effectiveness of multi-incision slings is well established; however, there are RCTs and other studies that go up to 17 years, but the FDA, specifically at that meeting, said the one-year data.
Q. Is the Nilsson/Ulmsten study an RCT?
A. No, it is not.
Q. Okay. Which one goes up to 17 years?
A. I --

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Q. Which RCT goes up to 17 years?
A. There are no RCTs that go to 17 years.
Q. How many long-term RCTs are there that study the TVT Retropubic device? Back up. What do you consider a long-term RCT?
A. I consider a long-term study at least three years by the International Incontinence Society's recommendations.
Q. There's not one for 17 years, as you just said, is there?
A. No.
Q. Okay. Let's go with this. Do you agree with that statement or not, Doctor?
MR. SNELL: Objection: Asked and answered.
THE WITNESS: I agree that this was on the FDA website. I feel that there is other data that looks at longer-term data than one year.
BY MR. KUNTZ:
Q. So you disagree with that statement?
MR. SNELL: Objection, asked and answered.
THE WITNESS: I believe it's well established for one year and beyond, yes.

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BY MR. KUNTZ:
Q. How many TVT Retropubic devices have been implanted?
A. Between 700,000 and a million worldwide.
Q. Okay. So no more than a million, right?
A. I would have to give a guess. I'm not --
Q. Where did you come up with 700,000?
A. I believe that there was a -- let me look through my position statement here. This may take me a second.
I'm going to pull this from Page 17 and this goes back to 2002. As of 2002, there were 200,000 TVT procedures performed with reference to Debodinance. As of 2006, there were over 700,000 TVT procedures performed worldwide, and that's Lord 2006.
Those will be two of the -- that's where I came up with the 700,000 number.
Q. Okay. Do you agree that the AUGS statement applies to all midurethral slings and not just the TVT Retropubic device?
A. No. Actually, it does not apply to the single-incision slings.
Q. Does it apply to TVT Abbrevo?
A. I think this was their position statement on midurethral slings in general. I'm looking to see

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if they talked about the FDA and the single-incision slings.
The only reference to that is they put -- in this document is explicitly stated: The FDA continues to evaluate the effects of using surgical mesh for the treatment of SUI and will report about that usage at a later date.
So they did not -- with this, they just -- this was a blanket on midurethral slings.
Q. What's the proper way to tension the TVT Retropubic device?
A. The TVT Retropubic device, after you pass the trocars through, you place a spacing device, when you are doing the adjusting, and you place a spacing device between the urethra and the mesh material. Once you cut these off, you then can have a patient cough with that device out to make sure, if they're awake, do they leak a couple of drops. And then the device is put back in and you pull the sheaths off.
Q. How do they cough under general anesthesia?
A. Under general anesthesia, you can do a Credé maneuver.
Q. Do you use minimal tension on the TVT Retropubic device?
A. What I do personally is I bring the mesh up

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to the spacing device.
Q. Do you tension it loosely?
A. I bring it to where it's just in contact so it will be loose.
Q. Okay. So you tension it loosely?
A. Yes.
Q. Do you believe that the TVT device is tension-free?
A. I believe that when it is placed is about as tension-free as you can get underneath the urethra, because there's actually a space between the urethra and the mesh.
Q. Do you agree that the strongest unmet need with the TVT is the ability to adjust tension both intraoperatively and postoperatively?
MR. SNELL: Form.
THE WITNESS: Could you -- could you -- could you repeat that question for me, please.
BY MR. KUNTZ:
Q. Do you agree that the strongest unmet -- strike that.
You talk to physicians about TVT Retropubic all of the time, don't you?
A. Yes.
Q. Have any of them ever told you their

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concerns about -- with the ability to adjust tension both intraoperatively and postoperatively; have you ever heard that?
A. I have heard the postoperatively. Intraoperatively I have not had.
Q. Okay.
A. That's new to me.
Q. Have you ever heard that that's one of the strongest unmet needs of the TVT device?
A. I -- I can't honestly say that I feel it's been an unmet need.
Q. Okay. Do you agree that the mesh in the TVT may be too wide?
A. I believe that it -- that it is studied and I have to go by the -- that level of evidence which is the same width.
Q. Okay. Do you believe that there's a risk the TVT mesh will fold on itself, roll up on a patient and cause discomfort?
MR. SNELL: Form.
THE WITNESS: I believe when it is properly placed, that it will not.
BY MR. KUNTZ:
Q. You've never seen anything to the contrary when it's properly placed?

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A. Not in my own personal experience.
Q. Okay. What about in the literature?
A. I had heard on an explanted that there may have been a folding, or something, yes.
Q. Where did you hear that?
A. That -- actually, that wasn't in the literature. That was a physician that when they had excised it felt that it was folded on itself.
Q. What physician? Who was that that you discussed that with, do you know?
A. It was at a meeting. I don't recall who.
Q. Do you agree there's no calibration to let you know when you have the TVT tensioned right?
MR. SNELL: Form, objection.
THE WITNESS: I believe that what we do is we do a test, either with Credé maneuver or having the patient cough, to see if there's a little bit of leakage of urine.
BY MR. KUNTZ:
Q. Okay.
A. But as in putting a device to measure tensioning, no.
Q. Okay. Have you ever heard that there is no consensus on the amount of tension needed and many feel the tension will vary based on the patient's

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presentation and patient anatomy?
MR. SNELL: Form.
THE WITNESS: I believe that if you have a spacing device, no matter what the anatomy, it is not in contact with the urethra and the placement.
BY MR. KUNTZ:
Q. Do you agree that there is some guesswork in adjusting the tension of the TVT Retropubic device?
MR. SNELL: Form.
THE WITNESS: Actually, no, I don't. Of all the procedures I've done it is probably the easiest to tension.
BY MR. KUNTZ:
Q. Do you think the tensioning is the same with both the mechanical cut mesh and the laser cut mesh?
A. I use the same spacing device in both --
Q. Okay.
A. -- for Retropubic.
Q. So is that a "Yes"?
A. Yes.
Q. If someone said that the laser cut mesh needed to be tensioned more loosely under the urethra, would you disagree with them?

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MR. SNELL: Form.
THE WITNESS: I would ask them to show me the study that was randomized to prove that.
BY MR. KUNTZ:
Q. Would you disagree with the physician if he had said that he had to laser cut mesh slings in much tighter than the mechanically cut ones?
MR. SNELL: Form.
THE WITNESS: I am not that physician. I wouldn't be able to say.
BY MR. KUNTZ:
Q. Okay. Would you disagree with that physician?
MR. SNELL: Form.
THE WITNESS: In my own personal experience, yes.
BY MR. KUNTZ:
Q. Okay. All of these studies that you reviewed, did you ever do an analysis of the studies that actually tracked long-term pain over six months?
A. What I did on the RCTs is I looked at the pain parts to it and also looked at the AUA information on pain in those patients.
Q. Okay. How many studies tracked pain over six months?

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A. There would be several that would include that in their complication rates. I'm going to look for the American Urology Association's paper that we had earlier. And this has been revised. This is 2009, but it's been revised.
And when they looked at their literature, they followed pain. In nine -- if you want, I can kind of go through --
Q. Sure.
A. -- each of these. In all Retropubic suspensions, pain 6 percent, sexual dysfunction 7 percent, voiding dysfunction 16 percent. So I'm going to exclude those. We don't have a breakdown on dyspareunia here or pain with intercourse, but the sexual dysfunction in Burch colposuspension, pain of 9 percent, sexual dysfunction of 7 percent, and then voiding dysfunction, again, 16 percent.
Q. And how long do they track the pain?
A. I would have to pull up their -- I don't have the whole sheet here. I would have to pull up their list.
Q. In all of this literature review, did you ever do your own analysis to see how many of these studies that you talked about decided to track pain over six months?

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A. They followed the pain and they reported that.
Q. You're not -- you're not following me. Did you ever look at all of these studies and do your own analysis to see how many of them tracked pain for over six months?
A. I -- what I did is if they had a meta-analysis, or whatever, I let the people that were doing those studies track that, but pain was listed as complications.
Q. Okay. And how long did they track pain in all of those studies?
A. Some of the studies -- I'm going to have to look so I don't misquote here.
So I'm going to go to the Ward/Hilton, on behalf of the UK and the Ireland QBT group, published in 2007.
I'm now going to go to Table 3, and this was a response -- before and after five years of surgery. Results are given in percentage reporting system.
On sexual questions, before surgery with TVT, they had 31 percent that complained of pain due to dry vagina. Afterwards, that was 19 percent. With colposuspension, it was 32 percent, and five

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years after 22 percent.
Pain with intercourse, pre-procedure would be thirty -- 34 percent. In TVT pre-op, 13 percent in five years. Burch colposuspension, 25 percent pre-op, 19 percent at five years.
So that -- that would be one of the ones I would quote.
Q. Okay. Ward/Hilton?
A. Yes.
Q. And I guess we can sit here all day and pull out all of these studies, but my question was: Did you ever do an analysis yourself of how many of these studies tracked pain --
A. No, I --
Q. -- over six months? That's my question.
A. Personal analysis, no. Did I read the literature where that was looked at, yes.
Q. Okay. But you don't know how many of those studies looked at pain postoperative or how many looked at pain after six months, correct?
MR. SNELL: Objection.
BY MR. KUNTZ:
Q. You never did that analysis? That's all I'm asking.
MR. SNELL: Objection: Form,

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misstates.
THE WITNESS: I did not do a systemic review of the literature because it had already been performed.
BY MR. KUNTZ:
Q. Do you know how many of these studies you cite in your report you brought here today include long-term pain as a data point?
A. I think that it -- I can't say an actual number, but when I look at the reports, if that was included in their analysis and in their follow-up, then, yes, I did.
Q. Can you point me to a long-term randomized controlled trial designed to look at the rate of chronic pain following implantation of the TVT Retropubic device?
A. There is no such study designed for that.
Q. Can you point me to a long-term RCT designed to look at the rate of chronic dyspareunia following implantation of the TVT Retropubic?
A. I believe that you have numerous studies that follow that. As in that being the absolute endpoint of the study, no.
Q. Can you hand to me or show me one long-term RCT for TVT that has safety as a primary endpoint?

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A. In --
MR. SNELL: Objection, form.
THE WITNESS: In these studies, whether it's randomized controlled studies or, especially, systemic reviews, what we look at, safety, which would include complication rates, mesh erosions and these things, are all included in those.
BY MR. KUNTZ:
Q. Okay.
A. So is there an RCT designed specifically? No. Is it in other parts of the literature that is very high quality? Absolutely.
Q. Okay. I'll ask you again. Hand me one study, long-term RCT, with the primary endpoint of safety.
A. There isn't any one. Safety is part of the studies but not the endpoint.
Q. Okay. Now, I think you told me, but not one study on the TVT Retropubic after 2007 you can tell me whether mechanical cut or laser cut mesh was used, correct?
MR. SNELL: Objection, form.
THE WITNESS: I am unaware -- I do not feel I would be able to tell you a study.

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BY MR. KUNTZ:
Q. Would you agree that the pores in the Prolene TVT mesh can collapse increasing the risk for erosion and bridging fibrosis?
MR. SNELL: Form.
THE WITNESS: No.
BY MR. KUNTZ:
Q. Okay. You disagree with that?
A. Yes.
Q. Do you disagree with that same statement for Prolene mesh in general?
A. I wasn't asked to evaluate Prolene mesh in general. I was asked to evaluate Retropubic TVT mechanically cut.
Q. Okay. Have you ever read anything anywhere that the Prolene mesh -- used in any capacity the mesh can collapse and increase the risk for erosion and bridging fibrosis?
A. I have read this; however, if it's an abdominal mesh, it wasn't what I was asked to review. TVT is a narrow strip, not a broad piece of material, and so that's almost like me telling I'm looking at my Model T and driving a Lamborghini. They're -- they are two different things.
Q. Okay. So you think mesh for the hernia is

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different than mesh for SUI?
A. I believe that the design of the mesh and the cut is different, yes.
Q. Do you know if the pores can collapse in the Prolene mesh when it's used for hernia application?
A. I have seen Klinge -- one second here, where he talked about hernia mesh, but also in his 2012 -- and I believe that is the right author. I -- let me look here a minute because one of the things when I reviewed it, it was on abdominal mesh, but in his 2012 he stated that TVT was a macroporous monofilament mesh and that was a gold standard for stress incontinence. I'm just trying to remember who the author was. It was a German author. I may have to -- I may spend quite a bit of time looking for this. I may have to --
Q. That's -- okay.
Do you agree, in general, if pores are not large enough, it increases the risk of erosion?
MR. SNELL: Form.
THE WITNESS: I believe that the Amid classification Type I states that the macroporous mesh is -- has less erosion and is better suited with biocompatibility, that as long as it's a Prolene

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polypropylene, Amid classification Type I, macroporous mesh. This is supported by SUFU, AUA, AUGS.
BY MR. KUNTZ:
Q. Do you agree that many physicians describe removing a sling as very difficult due to the amount of fibrosis?
MR. SNELL: Form, objection.
THE WITNESS: I have removed slings and I have found it to actually be much easier than such as an autologous swing because I cannot necessarily see the mesh, because it's completely incorporated, which is actually what I want, but what I do is I infiltrate with local anesthetic to develop tissue planes, and then I can take a nerve hook to catch the edge of the sling material, and then I can separate that off into -- and divide it. But when I pull that out, the tissue is completely incorporated into the material.
BY MR. KUNTZ:
Q. Have you ever talked to other physicians who have described removing the sling as difficult?
MR. SNELL: Form.
THE WITNESS: I have, and I've recommended some of the techniques that I have work

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for me.
BY MR. KUNTZ:
Q. Have you seen any internal Ethicon documents discussing the difficulty of removing slings?
A. I -- I believe that there are internal documents that discuss the difficulty, but the idea is --
Q. Sir, there's doctors that have difficulty removing slings. We can agree on that?
MR. SNELL: Form, foundation.
BY MR. KUNTZ:
Q. Well, you tell them -- you tell them to use your technique and it's easy, right? So --
A. If I --
MR. SNELL: Same objection.
Go ahead.
THE WITNESS: I feel that physicians can have difficulty because it is fully incorporated. However, this is the design of it; this is actually what we wanted the tissues to do.
BY MR. KUNTZ:
Q. Do you believe that the mesh -- the Prolene mesh and the TVT can degrade?
A. I'm not aware of -- when I'm looking at my

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high-level data that we are looking over time, that we're not seeing any clinical implication of it.
Q. That wasn't my question.
I can't tell from your report. You say everything degrades, Prolene mesh may degrade but no clinical complications. I just want to know: As you sit here today, do you believe that the Prolene mesh in the TVT degrades or not?
A. I think that anything you implant in the body can degrade over time.
Q. Okay. So the answer to my question is "Yes"?
MR. SNELL: Form.
THE WITNESS: I believe that we have 50 years of data --
BY MR. KUNTZ:
Q. That's not my question, Doctor, and you can tell Mr. Snell all you want when he asks you questions. My question simply is -- this is a yes or no question. Does the Prolene mesh in the TVT degrade?
A. From some of the internal documents, it showed that there may have been some cracking noted, but when they did other studies, it showed that -- depends how you -- how you describe degrading, but --

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and the chemical analysis showed that there was -- it was not changed. So I am a little bit -- I feel that personally anything you put in the body can age, just as we do, but I have to look at it, is it clinically significant.
Q. And we'll get to that. My question simply is: Do you believe, yes or no, that the Prolene mesh in the TVT degrades?
MR. SNELL: Objection, form.
THE WITNESS: I believe that over time anything you can implant into the body can degrade.
BY MR. KUNTZ:
Q. So the answer to my question is "Yes"?
MR. SNELL: Form, objection.
THE WITNESS: I -- I would believe -- I do not know the rate, but the potential would be there, yes.
BY MR. KUNTZ:
Q. You state in your report that you're not aware of any professional colleagues who have expressed concerns about degradation; is that true?
A. That is correct.
Q. Did you do literature -- complete literature search on degradation?
A. I -- when I go to the national meetings, do

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people see any of the clinical evidence that there's a problem with it, the answer is no. And that is supported by the studies.
Q. You never reviewed or seen any studies discussing clinical implications or problems with degradation of mesh?
A. I have not.
Q. Were you supplied --
A. I have seen from Taiwan where they removed a suburethral sling that they had done surgery on and they thought that there was some degradation there; however, that is a very small case study. It doesn't get into the level that I was asked to look at.
Q. Okay. So do you disagree with that paper?
A. I'm -- I am saying I was asked to review the best evidence available, and that is on the lowest tier.
Q. Okay. But did you -- did you -- did you review -- so are you saying you didn't review any articles that discussed degradation or degradation causing clinical impact or you just haven't seen any?
A. When I saw the study from Taiwan where they talked about it, but that is a small case series. That is not the level -- when you have level of evidence that's Level 1, that's a case series and a

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very small case series.
Q. And your best evidence is a long-term, post three years, randomized controlled trial, correct? That's the best evidence?
A. And the SGS systemic reviews and meta-analysis.
Q. As you sit here today, you've never been provided or you've never reviewed any articles suggesting degradation had any clinical complications?
MR. SNELL: Form.
Go ahead.
THE WITNESS: I am unaware in the high-level data that there's anything that suggests that.
BY MR. KUNTZ:
Q. Okay. What about any data? Besides the Taiwan study, the Wine (ph) study?
A. I have to look -- what I was charged with was using the best medical evidence on the safety and efficacy of the device, and that is randomized controlled studies, systemic reviews, meta-analysis, and I also look at data from national registries that have -- or something like the Kaiser system, to pull that data.

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Q. What other registries? You mentioned a couple in your report, right?
A. Yes.
Q. Okay. Like the Finnish registry?
A. The Austrian.
Q. Okay. How long did the Finnish registry track complications?
A. I would have to pull that data. This may take me a moment here.
MR. KUNTZ: Let's take a quick break.
(2:20 p.m. to 2:33 p.m. - Recess taken.)
THE WITNESS: I viewed over at least the one from Finland and that was a mediate postoperative complication of two months.
BY MR. KUNTZ:
Q. And that is the Kuuva study?
A. Correct.
Q. So it tracked pain for -- postoperative pain for two months --
A. Correct.
Q. -- at a maximum? Okay.
Did you review the Tamussino Austrian registry?
A. I will have to pull that up.

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Q. Okay. And we'll review that on the break.
Do you believe that you can see degradation of the mesh clinically?
A. No.
Q. Okay. How do you define degradation?
A. I really don't define degradation of the mesh. I -- when I look at it, if I am explanting it, that would be something that I would send to the pathologist so they'd be in formalin.
When they -- I cannot define when I'm looking at it if it's degraded.
Q. Okay. Have you ever read any articles that define degradation clinically --
A. No.
Q. -- being able to see it with your own eyes?
A. No, I am not aware of a high-quality article that shows that.
Q. Have you ever seen mesh that -- TV- -- strike that.
Have you ever seen mesh in general that you've pulled out that's brittle?
A. It's encapsulated in the tissue.
Q. Have you ever seen it when it's broken?
A. I have -- if it was broken, it's because I cut the mesh to remove it.

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Q. You say on Page 8 of your report that the mesh has antioxidants.
A. It is -- let me turn to Page 8, please.
And where -- oh, that's Page 9. Sorry.
It -- it's -- contains an antioxidant package.
Q. Okay. Why do you want to prevent oxidation?
A. There was -- when it comes to light, and everything, that you want to make sure that it does not become brittle. It is what I would kind of say.
Q. Would you believe that brittle mesh is degraded mesh?
A. I haven't seen brittle mesh, so -- in a patient and so I can't conjecture that. If I had a piece of plastic that was sitting in the sun and I folded it and it broke, I would say that was brittle.
Q. Would you say that's degraded?
A. I really don't know how I would call -- how it's degraded, I mean.
Q. Is it -- is it possible to do a randomized controlled trial to determine whether degradation occurs?
A. I think that that would be very difficult to do ethically, especially if you had patients that

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were completely asymptomatic.
Q. Would you agree there's authors out there or papers out there that have correlated pain to degradation?
MR. SNELL: Form, objection.
THE WITNESS: They -- there are authors that have suggested that. Again, what I need is the level of evidence to show that that has clinical implication and I have not found that.
BY MR. KUNTZ:
Q. Okay. So you disagree with those suggestions or those papers?
A. I do not see any clinical evidence.
Q. So you disagree with those authors that have suggested that?
A. I -- what I am saying is that I need a level of study that would convince me otherwise.
Q. And I understand that and I understand that you've never seen it in your practice of putting in 2,000 slings, correct?
A. Correct.
Q. But there are people who have written that they've seen it and that they've correlated pain with it; you understand that, right?
MR. SNELL: Objection, form.

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BY MR. KUNTZ:
Q. Have you seen --
A. Again --
Q. -- have you seen those papers?
A. -- their eyes must be very different than mine.
Q. You've seen the papers and authors that have suggested that, correct?
MR. SNELL: Objection, form.
THE WITNESS: It has been suggested by the authors, so that would be expert opinion which would be low-level data.
BY MR. KUNTZ:
Q. Okay. And you disagree with their opinions?
A. I do not have a quality of study that would indicate that I would agree with that.
Q. Okay. So you disagree with their opinions?
A. Yes.
Q. Okay. How late do you believe that erosions can occur in a patient with a TVT Retropubic sling?
A. Most of the studies show that they can occur up to about two years. There are occasional reports beyond that.

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Q. How far out do some of the occasional reports go that show it longer than two years?
A. I'm going -- I do not have an article specifically in mind that looks at that.
This may take me a little while here.
Q. Let me ask you this, Doctor. Do you agree that erosion can be a lifelong risk of a TVT Retropubic device?
A. I believe that if it has not happened by about three years, the risk would be incredibly small.
Q. So you think most erosions, when they occur, would occur within the three-year time period?
A. Usually within the first six months, yes.
Q. But up to three years?
A. I believe there was one reference to that as one report.
Q. So three years is that the most time you've ever seen for an erosion in the literature?
A. That is my recollection.
Q. And you're saying it can happen longer than three years, but it's a very, very low percentage possibility?
A. Yes.
Q. Okay. You talked about, in your report,

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about TOPA. Do you recall that?
A. Yes.
Q. What is TOPA?
A. TOPA was a compound mesh -- let me see. Do you have the page that that's referred to?
Q. Well, I can find it for you. I have it.
A. This is on Page 21. I'm going to read here. It says:
Randomized clinical trials evaluating meshes for the treatment of SUI do not support the theory that a change in the design of TVT would reduce or eliminate complications related to SUI. I'm aware that Ethicon evaluated a lighter weight, partially absorbable mesh called TOPA, but the project was unsuccessful because the mesh was too stretchy.
Q. Why was Ethicon developing TOPA?
A. They had lots of things in development, so I -- I wasn't involved with this at all, but I know at any one time they had multiple projects going on.
Q. Okay. That wasn't my question. My question was: Why was Ethicon developing TOPA?
A. I do not have a valid --
Q. Okay.
A. -- answer.

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Q. Did you review -- well, you didn't review any test- -- deposition testimony from any employees who worked on the TOPA project, correct?
MR. SNELL: Objection: Form, asked and answered.
THE WITNESS: I did not review depositions on those employees.
BY MR. KUNTZ:
Q. How many documents did you review related to TOPA?
A. I just reviewed over that they felt it was too stretchy, and so --
Q. That's what you remember reviewing?
A. That...
Q. What is Project Scion?
A. That I am --
Q. Have you ever heard of Project Scion?
A. I don't know.
Q. So that's a "No"?
A. I am trying to -- I do not recall a Project Scion.
Q. Okay. What is Project Matrix? Have you ever heard of Project Matrix?
A. I do not recall a Project Matrix.
Q. Did Ethicon ever -- do you know what a

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510(k) application is?
A. Yes.
Q. Did Ethicon ever submit a 510 application for the TOPA project?
A. That I am not aware.
Q. Okay. Did they ever submit one for the Matrix?
A. I -- I was asked -- I was not asked to review their submissions. I was asked to review the medical literature.
Q. Okay. Well, you have some other internal documents on your reliance list related to TOPA, right? And you talked about your understanding of what happened with TOPA and why it was canceled in your report, right?
A. I said that it was too stretchy.
Q. Okay. Did you review the 510(k) submission for project TOPA?
A. No, I did not.
Q. Did you review the 510(k) submission for -- strike that.
Do you know whether they submitted one for the Matrix project?
A. I do not recall.
Q. Do you know why the TOPA project was

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canceled?
A. I -- I do not recall.
Q. Do you know why the Matrix project was canceled?
A. I do not recall.
Q. Did you review any of the cadaver lab results for the TOPA project?
A. I -- I do not recall. I reviewed a large amount --
Q. If it's not on your -- if it's on your -- if it's not on your reliance list, you didn't review it, correct?
MR. SNELL: Objection, form.
THE WITNESS: I reviewed a large number of things. I just don't recall them all.
BY MR. KUNTZ:
Q. You just remember the document that says it was too stretchy? You remember that one, right?
A. I remember putting that into the...
Q. But you don't remember any of the other documents you reviewed?
A. I -- there was a large -- initially when I was doing this, I was reviewing internal documents and --
Q. And I think you said you spent ten hours

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total reviewing all of the internal documents?
A. I would say that's correct, yes.
Q. Okay. Did any of your ten-plus trips to the Ethicon headquarters or trips around the world for Ethicon, did you ever talk to any of the engineers or doctors who worked on the TOPA project?
A. I -- I don't know who worked on the TOPA project in-depth, but I may have.
Q. Okay. Do you know the size of the mesh that they used in the TOPA project?
A. No, I do not.
Q. Okay. Do you know the pore size?
A. No, I do not.
Q. Do you know the pore size of any other mesh besides the TVT Retropubic Prolene mesh?
A. What I look for is an Amid classification Type I macroporous mesh.
Q. Do you know the weight of the mesh used in TOPA?
A. I -- my -- I -- when talk about weight or these things, my concern is that AUGS, SUFU, everybody has agreed that using the Amid classification Type I macroporous polypropylene mesh has the best safety profile and best integration.
Q. Do you know the pore size of the mesh used

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in the Scion project?
A. I do not recall it.
Q. Do you know the weight of the mesh?
A. I do not recall.
Q. Do you know the material that was used?
A. I do not recall.
Q. Okay. You reference a Cammu (ph) study in your report?
A. Cammu study? Yes.
Q. What was that study?
A. Let me -- I'm going to need to pull that study, please. Could we pull the Cammu study on the flash drive, please.
Q. I wasn't even going to ask you about the study.
MR. SNELL: He's not asking --
BY MR. KUNTZ:
Q. Yeah, maybe I'll clear up. Aside -- that's the only study, I believe, that you cite regarding the use of absorbable or lightweight meshes for SUI?
A. Yes.
MR. SNELL: Form, objection.
Go ahead.
BY MR. KUNTZ:
Q. Have you reviewed any articles besides

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Cammu that discuss the use of absorbable mesh for the treatment of SUI, in a sling?
A. Actually, I can't cite a specific study, but the Vicryl meshes that were used did not hold up well.
Q. Okay. When you do a native tissue repair, do you use permanent or absorbable sutures?
MR. SNELL: Form.
THE WITNESS: I use permanent -- I use permanent sutures if I attach the rectus and then absorbable to attach the sling underneath the urethra so it does not move the fascia.
BY MR. KUNTZ:
Q. Do you know who Brigitte Hellhammer is?
A. I'm terrible with names.
Q. Do you know who Boris Batke is?
A. Again, I'm very terrible with names.
Q. You testified earlier, I think, that you have assumed some new positions recently?
A. Yes.
Q. What are those? Hold on. Are those on your CV?
A. No, they are not on my CV, so these are new. These are within the last two weeks.
I am medical director for the clinics at

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Shenandoah Medical Center. I am now on the board for an accountable care organization out of Des Moines.
MR. KUNTZ: I think I'm done for right now. You go ahead, Burt.
MR. SNELL: All right.
CROSS-EXAMINATION
BY MR. SNELL:
Q. Doctor, I have a few follow-up questions, and then I'm going to go see if I can cover things by topics.
You were asked questions about whether you reviewed certain hernia papers and documents or animal studies, and I believe you testified that you didn't find those relevant. Is that correct or not?
MR. KUNTZ: Objection, leading.
THE WITNESS: What I was tasked to do was to review the relevant medical data for efficacy and safety for Retropubic mechanically cut TVT. And when I looked at relevant data, I'm not operating on dollars. I am not doing abdominal hernia repairs. I'm having to look at the specific design of Retropubic TVT. So in looking at that data, that doesn't impact the scientific and medical literature for Retropubic TVT.

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BY MR. SNELL:
Q. So did you find dog studies, hernia literature, hernia documents relevant to your assessment of whether TVT, when used in women for treating incontinence, is reasonably safe?
A. It wasn't relevant to what I was asked by the judge to do.
MR. KUNTZ: I'm just going to strike that last comment. "Asked by the judge"?
BY MR. SNELL:
Q. Did you get a copy of the judge's order with regard what the parties --
A. Yes.
Q. -- were supposed to focus on in this particular case?
A. Yes.
Q. And I'm going to read it to you. This question: Does the design of TVT make the product not reasonably safe for its intended use; is that something you investigated?
A. Yes.
Q. All right. And what is TVT's intended use?
A. It is strictly for the treatment of mixed and stress urinary incontinence in women with Retropubic approach.

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Q. And you told Mr. Kuntz that you've used TVT Retropubic, correct?
A. Yes.
Q. For what was the intended use that you used the TVT Retropubic device?
A. Stress urinary incontinence and mixed urinary incontinence.
Q. The judge's order at Page 5 says the parties' primary focus should be the scientific and medical literature suggesting or contesting that the TVT is defectively designed and that it is not reasonably safe and can cause harm in women, et cetera. Is that something you investigated?
MR. KUNTZ: Objection: Form and leading.
THE WITNESS: Yes. And in doing so, what I wanted to do is to look at the highest-level evidence, which would be the randomized controlled studies, the systemic reviews, the meta-analysis, and cohort studies would be down that list, but anything below that I felt was lower-level evidence that did not pertain to this.
BY MR. SNELL:
Q. You mentioned a Dr. Klinge and I believe you testified you saw where the plaintiffs' experts

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had looked at some of the literature or writings he had done on hernias?
A. Yes.
Q. But you also testified that when it came to the intended use of TVT and the application of TVT for stress urinary incontinence, you had seen something different by Dr. Klinge?
A. Yes.
Q. I'm going to hand you a -- one of the Dr. Klinge's writings and we'll mark it for the record.
A. Okay. This is Page 440, Chapter 56, and it says Alloplastic Implants for the Treatment of Stress Urinary Incontinence and Pelvic Organ Prolapse.
Q. What, if anything, did Dr. Klinge discuss with regard to the use of TVT to treat stress urinary incontinence?
MR. KUNTZ: Objection.
THE WITNESS: States that the -- at the present, the gold standard for SUI surgery in suburethral sling, using either tension-free tape or transobturator tape. The initial concern is that the mesh used might lead to high rates of erosion did not hold true when macroporous polypropylene was used. In two long-term trials, erosion rate was 1.7 and 3.1

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percentage, respectively.
BY MR. SNELL:
Q. Does Dr. Klinge identify what type of mesh the TVT mesh is for the intended use of treating stress incontinence in women?
A. It says the classical TVT Type I, macroporous, monofilament, polypropylene mesh in the same trial.
Q. And what type of mesh is the TVT mesh used to treat stress urinary incontinence in women?
A. It is common Type I, macroporous, monofilament, Prolene polypropylene mesh.
Q. Is the Amid classification the current standard for identifying the type of mesh for the intended use of treating stress urinary incontinence?
MR. KUNTZ: Objection.
THE WITNESS: The national organizations, including American Urology Association, SUFU, AUGS, and also the NICE, all state it is Amid classification Type I.
(Exhibit No. 10 marked for identification.)
BY MR. SNELL:
Q. Is one of the things that you reviewed the most recent Cochrane review?

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A. Yes.
Q. By Ford and some other authors?
A. Yes.
Q. We have it here tabbed. I can take it out and mark it if counsel wants. Why don't we just do that.
(Exhibit No. 11 marked for identification.)
BY MR. SNELL:
Q. So I'm handing you the -- is that the most recent 2015 Cochrane review?
A. Yes, this is.
Q. What is a Cochrane review?
A. Cochrane review is a government-sponsored review to look at studies to develop recommendations and to look at the quality of the studies.
Q. You mentioned levels of evidence. Are levels of evidence important in assessing whether the TVT has utility and whether it's reasonably safe in the intended use of treating stress urinary incontinence?
A. Absolutely. That's --
Q. Why is that?
A. That is the highest-level medical evidence that is available and that's how I have to counsel my

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patients. This is how, when I am lecturing, I can present the best data available, and the Cochrane reviews and RCTs allow me to do that.
Q. Are the Cochrane reviews, the RCT, the systematic reviews you've mentioned by the AUA and SGS reliable, in your opinion, in determining the efficacy and the reasonableness of the safety of TVT to treat stress urinary incontinence?
A. Yes.
MR. KUNTZ: Objection.
THE WITNESS: The highest -- they are the highest level of evidence.
BY MR. SNELL:
Q. And this new Cochrane review, if we turn to Page No. 10, does the newest Cochrane review discuss what is the standard for mesh classification to treat stress urinary incontinence, mesh in women as of 2015?
A. What they did is they broke down into macroporous, microporous, macroporous multifilament, and submicronic.
(Reading:) And Type I mesh has the highest biocompatibility for least propensity for infections. Differences in their efficacy and complications are likely due to several different factors including the

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different knits and weaves of the various tape materials, their biomechanical properties and their histologic biocompatibility. Pore size affects the inflammatory response and resultant connective tissue formation within and into the mesh, and the rearrangement of the materials such as collagen within the mesh structure. Macroporous meshes, pore size in excess of 75 microns, easily allows macrophages, leukocytes, fibroblasts, blood vessels and collagen to transverse the pores, thus macroporous meshes promote tissue host ingrowth with resultant biocompatibility and low risk of infection. Monofilament tapes are widely available and -- and are now predominate in current clinical practice.

Q. Did you assess the biocompatibility of the TVT mesh utilized in the TVT device to treat stress urinary incontinence?

MR. KUNTZ: Objection.

THE WITNESS: I assess it every day in my patients and postoperatively.

BY MR. SNELL:

Q. And did you assess the medical literature and the scientific literature with regard to the use of the TVT and its biocompatibility in treating stress urinary incontinence?

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A. Yes, I did.

Q. And what did you find?

A. I found that the highest-level evidence available in the medical literature, most of the studies involve TVT Retropubic, the classical mechanical cut.

Q. And did the Cochrane reviews, the systematic reviews, the incontinence guidelines show whether or not TVT mesh to treat stress incontinence in the TVT device is biocompatible?

A. Yes.

Q. And what did those Level 1 evidence show overall in general with regard to the usefulness or utility of the TVT?

A. The randomized controlled studies, these large studies, showed that the Retropubic TVT is the most studied -- high-quality study of literally on a urological gynecological procedure.

Q. Did those studies demonstrate whether or not the TVT is useful and that it is efficacious in treating stress urinary incontinence?

A. Yes.

Q. Did those studies assess the safety of TVT for the treatment of stress urinary incontinence?

A. Yes, both in the short term and in the

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longer term on the follow-ups. These patients are followed serially, and when we look at clinical complications or clinical utility, is what is this instance, is it acceptable as a surgeon, because everything we do as a surgeon has potential risks and complications.

(Exhibit No. 12 marked for identification.)

BY MR. SNELL:

Q. So you were discussing biocompatibility. Are you a biomaterials expert with regard to materials utilized in women to treat stress urinary incontinence?

MR. KUNTZ: Objection.

THE WITNESS: Yes. I use it every day. I am the end user, the implanter. And more importantly for me is the implantee, and so when I implant this in any woman, I have to use the best available data to counsel that patient. And so in being an end user, yes, I am.

BY MR. SNELL:

Q. Do you assess the biocompatibility of a TVT device to treat stress incontinence in your patients for whom you implant that device after implantation?

MR. KUNTZ: Objection.

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THE WITNESS: Not only postoperatively but at any follow-up visits; I always assess exit wounds, the suburethral incision, and also the trajectory along the urethra.

BY MR. SNELL:

Q. Do you assess the patient's reaction to the mesh?

A. I ask: "Is it working? Are you having problems?" I ask specifically about voiding dysfunction, pain, dyspareunia. That is my standard questionnaires I have even if it's ten years ago and I see them.

Q. Do you do vaginal examinations on women for whom you have implanted the TVT device to assess how compatible that device is working in the woman's body?

A. I do because if there's an erosion or any complication or even tenderness over the area.

Q. I think you mentioned earlier the SGS, the systematic review. I just want to mark that as Exhibit 12. Is that the systematic review you were earlier referencing?

A. Yes.

Q. And Table 3 has rates of complications for various stress urinary incontinence procedures?

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A. Yes.
Q. And does that report on the Retropubic TVT --
A. Yes, it does.
Q. -- applies to treat stress urinary incontinence?
A. Yes.
Q. Is that something you relied upon in formulating your opinions?
A. In formulating -- yes.
Q. What level of evidence is the systematic review?
A. This would be the highest level.
Q. And what, if anything, does that systematic review show with regard to the risk of dyspareunia exposure and wound, you know, infection complications with TVT Retropubic compared to other procedures --
MR. KUNTZ: Objection.
BY MR. SNELL:
Q. -- if anything?
MR. KUNTZ: Objection.
THE WITNESS: In the Retropubic approach, the incidence of dyspareunia of 0 percent. For return to operating room for erosion for pubovaginal -- excuse me, Retropubic sling would be

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1.9 percent, pubovaginal 1.6. For incidence of exposure, Retropubic was 1.4 percent and pubovaginal of 5.4 percent.
BY MR. SNELL:
Q. How is it that pubovaginal slings -- those are the autologous ones you mentioned earlier?
A. Yes.
Q. Can they erode into the body -- into a woman's body when used to treat stress incontinence, as well?
A. Yes.
Q. What about wound infections or wound complications?
A. The wound infection rate for pubovaginal sling, that would be Table 3--I just changed from Table 2--12 percent incidence for pubovaginal for wound infection.
Q. Okay.
(Exhibit No. 13 marked for identification.)
BY MR. SNELL:
Q. I'm handing you Exhibit 13, which is Appendix A16 from the AUA guidelines, Complication Rates, No Prolapse. Do you see that?
A. Yes.

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Q. Does this report on the rates of pain in sexual dysfunction with autologous slings, the Burches and the midurethral slings?
A. Yes.
Q. And how does the midurethral sling, particularly like the TVT Retropubic device to treat stress urinary incontinence, compare to autologous slings and the Burch for pain in sexual dysfunction in women?
A. I will first go with Burch colposuspension, pain 6 percent, sexual dysfunction 3 percent. For autologous fascia without bone anchors, pain 10 percent, sexual dysfunction 8 percent. And for mid- -- synthetic at midurethra, for pain 1 percent, sexual dysfunction 0 percent.
Q. So are the rates with TVT, the midurethral sling, lower than the Burch and autologous --
A. Yes.
Q. -- for pain and sexual dysfunction?
A. Yes.
Q. And is that consistent or inconsistent with your overall evaluation of the safety of midur- -- of the TVT Retropubic sling to treat stress incontinence?
A. It is consistent with my literature review

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and also my personal experience.
(Exhibit No. 14 marked for identification.)
BY MR. SNELL:
Q. I believe you earlier mentioned there were some longer-term studies with the TVT Retropubic device?
A. Yes.
Q. I want to show you a paper by the author Serati, S-E-R-A-T-I, et al.
It's been marked as Exhibit No. 14. Just I first ask you: Is that a paper you've reviewed --
A. Yes.
Q. -- in your assessment of the TVT as a device to treat stress urinary incontinence for women?
A. Yes.
Q. And what, if anything, did that study show with regard to the utility of TVT at ten years' duration?
A. The ten-year subjective, objective, and urodynamic cure rates were 89.7 percent, 93.1 percent, and 91.4 percent.
Q. And how does -- strike that.
For a ten-year incontinence rate,

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urodynamic, subjective cure rates around -- all around 90 percent, what, if anything, does that tell you about the long-term biocompatibility intolerability of the TVT to treat stress incontinence in women, if anything?

MR. KUNTZ: Objection.

THE WITNESS: That at ten years it is still working as intended.

BY MR. SNELL:

Q. Is that data consistent or inconsistent with the theory of degradation of the mesh?

MR. KUNTZ: Objection.

THE WITNESS: I do not -- this reinforces the idea that clinically we do not see degradation affecting outcomes.

BY MR. SNELL:

Q. I know you probably already testified. I think you said that there is always a possibility that something may happen considering our bodies as they age. Do you recall giving testimony along those lines?

A. Yes.

Q. Have you seen any reliable scientific studies and evidence assessing TVT for the treatment of stress urinary incontinence that show that that

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product degrades?

MR. KUNTZ: Objection.

THE WITNESS: No. No, I am not aware of any.

BY MR. SNELL:

Q. And do the long-term studies that you have reviewed on TVT support the contention that the mesh degrades?

A. No, it does not. It does not impact the clinical utility.

Q. Turn, if you would, at Page 39 of your expert report. Just so I have a copy, let me --

At Page 39 of your report, did you assess the long-term literature with regard to TVT and its intended use to treat stress urinary incontinence?

A. For Retropubic TVT, yes, I did.

Q. And on Page 39 at the top, do you discuss multiple different studies that assess the TVT Retropubic device in the treatment of stress incontinence in women?

A. Yes.

Q. What do those studies show, if anything, in your mind?

A. What this shows in the long term that the continence rates still maintain over time.

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In the past, before Retropubic TVT, when I counseled my patients, I told them that over time that there will be more failures. And this is one of the reasons, when this came out, that I was really looking at it. I wanted to make sure that we were looking at long-term success rates. And the data here, whether it's Nilsson's at 17 years, even though that's not an RCT, this is long-term data, but when you talk 17 years, 13 years, 10-plus years, the success rates are in the 80s to 90s in these patients. There are some that are a little bit lower in the 70s but significantly better than anything I could offer in the past.

Q. And what is the patient satisfaction like for the women who undergo implantation of TVT Retropubic to treat their stress urinary incontinence?

MR. KUNTZ: Objection.

THE WITNESS: I ask my patients when they come in: "How are you doing?" And, "Would you recommend this to your friend, your sister, an acquaintance?" And almost always it is, yes, that the impact in their life was immediate. That's one of the reasons the impact on these women's lives from the surgical procedure is so profound that it's one

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of the most rewarding things I've done.

BY MR. SNELL:

Q. On Page 39 of your report, do you assess the randomized control trials and clinical studies that assess TVT in the treatment of stress urinary incontinence in women?

A. Yes.

Q. And in particular, did you assess what the patient satisfaction rates were with TVT?

A. Yes.

Q. And can you just in general summarize your overall impression about, you know, what rate of patient satisfaction was there in the literature that you have accumulated on Page 39 of your report?

A. From the low 80s all of the way up to the upper 90s satisfaction rates.

Q. Is that consistent or inconsistent with your clinical experience?

A. That is --

MR. KUNTZ: Objection.

THE WITNESS: That is very consistent with my clinical.

BY MR. SNELL:

Q. What, if anything, does the 80 to 90 percent patient satisfaction rate, even in

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long-term follow-up, say with regard to the biocompatibility of the TVT device in women when used to treat stress incontinence?

MR. KUNTZ: Objection.

THE WITNESS: That it is still continuing to work and that they are not having complications that are affecting their lives.

BY MR. SNELL:

Q. I think you told Mr. Kuntz, earlier you had used different types of meshes in the application, the intended use to treat stress urinary incontinence?

A. Yes.

Q. And can you just tell us, again: What's your -- what different types of meshes have you utilized to treat stress incontinence over your career?

A. Mersilene, Gore-Tex. I did use a couple hand-knitted Vicryl meshes. And each of those just did not seem to work.

Q. In your assessment of the literature, did you examine whether there was any mesh that had been demonstrated to be more biocompatible than the TVT Retropubic mesh in the treatment of stress urinary incontinence?

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MR. KUNTZ: Objection.

THE WITNESS: I did not find anything that was more biocompatible. Also, you have something that has been utilized in humans for over 50 years, along with FDA changing from a Class 3 to a Class 2 for Prolene. I have also assessed as I used to do a significant number of tubal reversals, and I've seen those patients laparoscopically, and looking at where the sutures are located laparo- -- these are small sutures, but the body of the literature shows tremendous biocompatibility.

BY MR. SNELL:

Q. Has any mesh been demonstrated in reliable scientific evidence to have either higher success than the TVT Retropubic device to treat stress urinary incontinence -- go with that one, first.

A. I am unaware of any device or any mesh that has a better subjective and objective cure rate or improvement rate in the literature.

Q. Have you seen, in Cochrane reviews and other meta-analyses, where mesh has -- or devices other than the bottom-up TVT actually have lower efficacy than TVT?

MR. KUNTZ: Objection.

THE WITNESS: Could you rephrase that, please.

MR. SNELL: Yeah, that's a bad question.

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BY MR. SNELL:

Q. Have you seen in the medical literature whether non-Type I macroporous meshes, such as multifilament meshes, have lower efficacy than TVT?

A. Yes.

Q. Have you evaluated the literature to assess whether the multifilament meshes and the non-Type I meshes have higher complication rates than the Type I TVT mesh you've been talking about today?

A. Yes, not only in literature but personal experience.

Q. Okay. And what does that literature show with regard to the meshes other than TVT that are non-Type I?

A. Much high erosion rates is one of the big things, along with pain and infections.

Q. And does the literature describe why those higher complications are seen with the design of those meshes as compared to the design of the TVT Retropubic mesh?

A. I have to go back to the Amid classification where you have macroporous mesh size

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of at least 75 microns so the body can integrate in and around and through the mesh.

Q. Are you an expert in the design of TVT Retropubic and, in particular, for assessing the utility and safety of it for its intended use to treat stress incontinence?

MR. KUNTZ: Objection.

THE WITNESS: Yes. I have taught numerous surgeons the procedure, so on that aspect, I may not be a chemical engineer but, on that, absolutely. Also, in the development of these products, I worked with the engineers as an end user for my input.

BY MR. SNELL:

Q. Did you read the medical literature with regard to the design and development of TVT by Drs. Ulmsten and Petros and determine whether or not in the design of TVT to treat incontinence those surgeons tried other materials besides the Prolene polypropylene?

A. Yes, they --

MR. KUNTZ: Objection.

BY MR. SNELL:

Q. And what, if anything, did that data show with regard to the other materials that they tried to

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use in the TVT device to treat stress incontinence?
A. With the Type -- Type III meshes, that they found significantly higher erosion rate, and that very much correlates to my own personal experience with this.
Q. Do you know whether they had tried meshes, such as Gore-Tex, before the Prolene?
A. Gore-Tex and Marlex mesh were two of the ones that they did utilize. And then they also then looked at the polypropylene meshes at that point, and they did a study where they had in the arms of Marlex and polypropylene macroporous.
Q. Do you know if those doctors in the design of TVT Retropubic device to treat stress incontinence also assessed a mesh called Mersilene?
A. Yes.
Q. And what was found with Mersilene in the design of TVT?
A. A significant erosion rate.
Q. You were asked some questions about mechanical cut and laser cut mesh. Have you used both of those different types of cutting of the TVT mesh?
A. Yes.
Q. In your opinion, does -- and just so that

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everyone is clear, when a mesh is mechanic -- let's focus on the TVT mesh and not the other meshes you say are not relevant.
When you cut the TVT mesh, where are you cutting it when you're mechanically or laserly cutting it?
MR. KUNTZ: Objection.
THE WITNESS: On the edges.
BY MR. SNELL:
Q. The very edge?
A. Yes.
Q. Is the mesh still about 1 centimeter wide?
A. Yes.
Q. Does the cutting of the mesh, either mechanically or with a laser, change the way the mesh handles and operates in the body when used to treat stress incontinence?
A. I do not feel that either way impacts how I implant or how I treat my patients afterwards. The longest-term data I have is mechanical cut.
Q. And what does that long-term data show with regard to the mechanical cut TVT mesh?
A. The complication rates are very low and that the long-term success rates are very robust.
Q. Now, I think you mentioned to Mr. -- or

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Mr. Kuntz that you had seen company documents and testing where they had mesh and was stretching it on clamps?
A. Yes.
Q. Is that the use of TVT to treat stress incontinence, that testing?
A. No, that's benchtop testing. That has really nothing to do when I'm implanting the mesh. That's an actual deliberate deformation. I don't understand all of the properties there, but it does not impact when I place it in a patient.
Q. When you place a TVT Retropubic device and that mesh in a patient, is there a sheath on the mesh?
A. Yes.
Q. Is the pathway by which the mesh and the sheath travel, do they follow a trocar?
A. Yes.
Q. Do you believe that benchtop testing of a mesh -- and when you saw the benchtop testing, let me ask you this, was the sheath on the mesh?
A. No.
Q. Was the trocar on the mesh?
A. No.
Q. Do you believe that that benchtop testing

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in stretching the mesh without the sheath is consistent with the intended use of the TVT device to treat stress incontinence?
MR. KUNTZ: Objection.
THE WITNESS: The sheath is on the mesh and that because it is on the mesh that is its intended use, and so the sheath needs to be present from a clinical standpoint and an implantation standpoint for Retropubic TVT.
BY MR. SNELL:
Q. And whether it's a mechanical cut mesh or a laser cut mesh, is the mesh, when it's put into the body of a woman in the intended use of stress incontinence, encased in a sheath?
A. Yes.
Q. Do any of the stress urinary incontinence guidelines or the analyses and position statements by the professional societies state that there is any clinically significant difference between mechanical and laser cut TVT mesh?
MR. KUNTZ: Objection.
THE WITNESS: No. No, they do not.
BY MR. SNELL:
Q. Have you assessed the literature before 2007?

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A. Yes.
Q. Have you been assessing the literature since 2007 with regard to TVT?
A. Yes.
Q. Is there any clinically significant difference that you have seen in the medical literature before and after laser cut was an option with regard to the utility or safety of TVT?
MR. KUNTZ: Objection.
THE WITNESS: I've seen no differences in the literature.
BY MR. SNELL:
Q. Is consistency in the literature something you look to as a scientist?
A. As a scientist and as a clinician.
Q. Why is that important, if at all?
A. What you have to do is you have to have reproducibility. Just as you have -- in baseball you have people who are phenomenal pitchers. In medicine you also have phenomenal surgeons, but you have to have the randomized control reproducible studies in order to be able to draw a conclusion.
Q. And do you believe -- and I think you discussed in many pages of your report the reliable scientific evidence you found. Did you believe was

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in -- was relevant and important in assessing the design of TVT?
A. Absolutely.
Q. Are the long-term ten-year -- strike that.
Are the majority of the 5-, 7-, 10-, out to 17-year, the longer-term studies with TVT, do those studies utilize mechanically cut mesh?
A. The longer terms are all mechanically cut.
Q. And what, if anything, do they show about the utility and safety of the mechanical cut TVT mesh?
MR. KUNTZ: Objection.
THE WITNESS: They state that the efficacy continues and that we do not see increasing erosions or anything along or other complications with that, so --
BY MR. SNELL:
Q. Go ahead. I didn't mean to cut you off.
A. It implies very strongly that -- when I'm counseling my patients, that I can look at them in the eye and say, the 10-year data up to 17 years, variability and rate, that it looks like this is going to last you in the long term.
And when I'm talking with my patient, that's what she needs to know, along with the

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perioperative and intraoperative complications.
Q. Okay. So did you assess the safety of TVT, not just within the perioperative setting but also postoperatively, including years of follow-up?
A. Yes, and then when we look at these RCTs and we look at the follow-up, that is part of what we are assessing, is are we having new onset of complications. You know, we like to look at the safety perioperatively, but we also want to make sure that in the long run it continues to work well.
And the level of evidence -- one of the reasons I looked at suburethral slings was when I looked at my patients and I did a major procedure, I would have to look them in the eye and say, I'll probably see you back. And the redos of Burches are -- can be very, very difficult procedures. And I use slings as my backup for that, but I, again, harvesting autologous slings and complications that occur with that, also the bigger incisions, I was always looking for the better, and even today, I'm hoping that we can find a better TVT.
Q. Is there -- you were -- I think you told plaintiffs' counsel you were doing the Burch and you had done autologous slings long before TVT to treat stress incontinence?

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A. That is correct.
Q. As we sit here today, is there even more data on the TVT Retropubic device to treat incontinence than there are for those older Burch and pubovaginal slings?
A. Much better high-level quality evidence.
Q. Going back to the Exhibit 14, the Serati 10-year TVT paper, did those authors assess the safety of TVT even out at ten years?
A. Yes.
Q. And what did they find, if anything, that is significant to you?
A. This is on Page 942, European Urology, and it would be 61 and 2012:
No patient required tape release or section during the ten-year follow-up. No significant pelvic organ prolapse, vaginal, bladder, or urethral erosion, or de novo dyspareunia were noted in the remaining 58 patients.
Q. What's the importance of that, if anything, to you in your overall assessment of the safety of the design of the TVT Retropubic device?
A. That years down the road I've not seen complications and my patients are not experiencing that.

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Q. Plaintiffs' counsel asked you some questions earlier about your usage of TVT and how many TVTs you had done, correct?
A. Yes.
Q. And I believe you testified the number was 2,000, give or take 500?
A. Yes.
Q. Are you certain that's how many TVTs you've placed over your career?
A. All TVTs?
Q. The TVT Retropubic device?
A. The TVT Retropubic device --
MR. KUNTZ: Objection.
THE WITNESS: -- I would say is about in that range.
BY MR. SNELL:
Q. For example, did you undergo any training or exposure to the TVT Retropubic before you began utilizing it as an option --
A. Yes.
Q. -- for stress incon- --
A. Yes.
Q. And did you keep track of how frequently you did TVT Retropubic devices once you began doing it on a monthly or yearly basis?

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MR. KUNTZ: Objection.
THE WITNESS: I kept a running mental log.
BY MR. SNELL:
Q. Just like you would have kept a running mental log of how many Burches or autologous slings you did --
A. Yes.
Q. -- before that?
A. Yes.
Q. The fact that you didn't write down the exact number you did in a certain month or year, does that make your estimate unreliable with regard to the number of TVT Retropubic devices that you have used in your career?
MR. KUNTZ: Objection.
THE WITNESS: No. I think that it's a ballpark figure that is probably fairly close.
BY MR. SNELL:
Q. Such that there is no doubt in your mind whatsoever that you -- do you believe you have extensively used the TVT Retropubic device to treat stress incontinence in women?
A. Yes.
Q. For your complication rates, did you follow

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your patients in order to assess whether or not they had complications after the TVT Retropubic device?
A. Yes.
MR. KUNTZ: Objection.
BY MR. SNELL:
Q. Is that actually something -- strike that.
Did you follow your patients who you put -- who you did a Burch procedure or an autologous sling or some other type of non-Type I macroporous sling and to treat incontinence?
A. Yes.
Q. Did you follow them to see if they had complications?
A. Yes.
Q. Did you track those complications?
A. In my -- I did not put them necessarily on paper, but in the patient record I would have that.
Q. This is your -- is this your general medical recollection and knowledge of complications that your patients have?
A. Yes. I would -- I would -- the only time I would look at specific complications is if I was doing a study.
Q. Okay. And did you assess the overall medical literature and data that you found to be

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scientifically reliable to ascertain the rates of complications with TVT Retropubic device?
MR. KUNTZ: Objection, asked and answered, at least eight times.
MR. SNELL: Well, I'll withdraw if he's answered it.
MR. KUNTZ: I mean, it's in his report and he's answered ten times.
THE WITNESS: Please repeat that, if you would. I -- it was a little long, so please restate it. It's getting towards the end of the day.
BY MR. SNELL:
Q. Okay. Did you assess the medical literature that you found to be scientifically reliable and valid with regard to what were the complication rates following a TVT device -- Retropubic device placed to treat stress incontinence?
A. Yes.
Q. Did you also look at the literature to assess how those rates compared to rates with the Burch colposuspension or the autologous sling?
A. Yes, and I wanted to expound a little bit on that, is when we look at these complication rates, this is over a 26-year history of treating women, and

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so when I'm looking at older data comparing -- early on in my career, I may have pulled up Burch's initial paper on it, and I'm looking to see, am I hitting in that area, or I would talk to Ray Lee and say, "I've seen this. What should be the expected rates?"

And so this is a 26-year evolution. When I was in residency, randomized controlled studies really were not the norm.

Q. As we sit here today, there are, I think you've testified, numerous randomized controlled studies on the TVT Retropubic device?

A. Yes.

Q. Is there any other device or procedure to treat stress urinary incontinence for which there is more randomized control trial data than the TVT Retropubic device?

A. No.

Q. You were asked questions about some of the registries. At Pages 33 through 36 in your report, do you cite to and discuss some of the registries, like the Schraffordt registry that had three years follow-up?

A. Yes.

Q. And did you look at another registry by Nilsson that reported 12-month data from over 2,000

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TVT patients?

A. Yes.

Q. You also cite to Svenningsen, S-V-E-N-N-I-N-G-S-E-N. What was the follow-up with that TVT registry?

A. That says ten-year results.

Q. And what did that study show with regard to the long-term ten-year biocompatibility of the TVT Retropubic device?

A. Objective cure rate was 89.9 percent, excuse me, subjective cure rate of 76.1 percent, 82.6 percent of patients stated they were very satisfied with their surgery. And also in Svenningsen it said, "Midurethral slings are currently considered the gold standard in the surgical treatment of SUI."

(Exhibit No. 15 marked for identification.)

BY MR. SNELL:

Q. Okay. So you've been handed Exhibit 15. Is this the ten-year TVT study that you referenced on Page 35 of your expert report?

A. Yes.

Q. And on the first page, first paragraph, where they talk about midurethral slings are the gold

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standard, is that what you were referring to earlier?

A. Yes.

Q. And if you look at -- turn back to the back to Table 4.

A. Table 4, yes.

Q. Do they report on long-term outcomes -- complications such as mesh exposure, voiding difficulties, things of that nature?

A. It's ten years and then they look at voiding residuals, they look at mesh exposure rate, subjective voiding difficulties; and then they also break it down -- the subjective voiding difficulties into slow stream or intermittency, position-dependent micturition, need to immediately re-void, incomplete bladder emptying feeling, straining to void, hesitancy.

Q. It says asymptomatic vaginal mesh exposure, there was one patient equaling 0.3 percent; do you see that?

A. That is, yes.

Q. What, if anything, does that tell you about the long-term safety of TVT Retropubic device in the treatment of stress urinary incontinence?

MR. KUNTZ: Objection.

THE WITNESS: What that tells me is

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we're not seeing exposure over the long run which we saw with other meshes.

BY MR. SNELL:

Q. Other meshes such as what?

A. Marlex mesh.

THE WITNESS: Can I ask if I can have a bathroom break?

MR. SNELL: Yes, you may. Go ahead.

(3:39 p.m. to 3:44 p.m. - Recess taken.)

BY MR. SNELL:

Q. You were shown Exhibit 9. It was a contract dated November 23rd, 2010. You -- do you recall that?

A. Yes.

Q. My question is simple. This contract says that it shall continue to January 31st, 2012. Do see that in Paragraph 1?

A. Yes.

Q. Is this a 2010 prof. ed. contract or a 2011 contract?

A. It would be -- so that would be for the year 2011.

Q. Okay. You were asked questions about, you know, moneys you were paid, you know, in your

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consulting for Ethicon. Let me ask you. And I think a question was asked were you paid during your travel. My question to you is this. Were you paid for your time for when you left your house or your office until you returned?

A. No.

Q. How were you compensated or reimbursed as a consultant?

A. I am not sure of what year that they started paying for travel time, but it was very late in this whole cycle. But if I traveled two days but only did a half day of lecture, I got paid a half day, so I was two days out of the office in that case. But when I drove to the airport, when I was on the plane, checking in at a hotel, getting a cab, I was not reimbursed for any of that time.

Later on, they actually did a travel time, but that -- I don't remember what year that kicked in, but it wasn't for the vast majority of the time.

Q. Can you give us your best estimate, would that have been within the last five years or was that --

A. I would probably say --

Q. Just let me get my question in.

-- was that when you began doing consulting

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on the TVT Retropubic device?

A. No. It would have been after that time.

Q. You, I believe, earlier stated it was financially challenging for the consulting work at times. Did I hear you correctly or did I not?

A. Yes.

Q. What did you mean by that?

A. I was in solo practice so my overhead stayed the same whether I was there or not, and so I had ongoing expenses, and if those weren't reimbursed -- you know, if I was gone the two days, I got reimbursed for half a day, and my ongoing expenses were not covered.

(Exhibit No. 16 marked for identification.)

BY MR. SNELL:

Q. Take a look at this. I've handed you Exhibit 16. It's a study by Neuman. Turn, if you would, to the second-to-last page where it talks about dyspareunia in the TVT Secur group.

A. Yes.

Q. Do you see where the authors say or they paused that there may have been more dyspareunia in the laser cut mesh which tends to result in a stiff tape edge. Do you see that?

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A. I'll go ahead and read this paragraph. This is Page 772. This is a Journal of Minimally Invasive Gynecology.

Q. Is this a study you've seen, first of all?

A. Yes.

Q. Okay.

A. And --

Q. Go ahead.

A. -- Volume 18, No. 6.

It says:

Dyspareunia occurred only in patients who underwent TVT Secur procedure. The pain was relieved after surgical removal of the involved tape segment. Dyspareunia associated with the TVT Secur procedure might be explained in part by the rigidity and reduced flexibility of the synthetic polypropylene implant because it is laser cut, which tends to result in a stiff edge -- tape edge. As a result, the overlying vaginal mucosa is constantly traumatized, much more than it would be with use of a mechanically cut tape.

Q. So plaintiffs' counsel asked you if you had seen any studies, and I want to focus now on: Have you seen any scientifically reliable studies assessing TVT in the treatment of stress urinary

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incontinence where any author in the world stated there were higher complications with the mechanical cut TVT mesh compared to some other form of cut mesh?

MR. KUNTZ: Objection.

THE WITNESS: I am not aware of any studies.

BY MR. SNELL:

Q. And in your assessment of the overall literature for devices to treat stress urinary incontinence, particularly meshes, did you find any other device that used an alternative to mechanical cut mesh that had a better safety profile than the TVT Retropubic mechanically cut mesh?

MR. KUNTZ: Objection.

THE WITNESS: No.

BY MR. SNELL:

Q. Did you provide professional education on the TVT Retropubic device to treat stress incontinence?

A. Yes.

Q. Did you provide that to other surgeons?

A. Yes.

Q. Did you talk to other surgeons about the design of the TVT Retropubic device?

A. Yes.

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Q. Did you talk to other surgeons about the components of the TVT design?
A. Yes.
Q. Did you explain to other surgeons the importance or lack thereof, if any, to the various components of the TVT Retropubic device?
A. Yes.
Q. Did you discuss the importance, if any, with the sheath utilized in the TVT device?
A. Yes.
Q. Was the sheath an important design element of the TVT Retropubic device?
A. Yes, and I would like to expound a little bit upon this.
Q. Go for it.
A. When I initially looked at TVT Retropubic, I was very concerned about the possibility of bacterial contamination.
Having the sheath there somewhat alleviated that, but what -- when I was looking at this, I was thinking, if we have bacterial contamination, we'll be seeing infections very rapidly; and I didn't see that.
I also had spoken with the surgeons when they were using Gore-Tex patches for hernias, and

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they were finding an increased infection rate and were they seeing that with the polypropylene mesh.
So in that evolution, I was looking at what the Amid classification said, what my surgeons were saying. Also having that plastic sheath did provide a little bit more of what I would call comfort in looking at it. At this point, I'm very comfortable with the mesh, but I -- I had mesh complications of other types that I was very concerned about.
Q. And were those all meshes that had --
A. They were --
Q. -- either a smaller pore than the TVT mesh or they were non-Type I Amid, microporous, monofilament meshes?
A. They were all non-Type I on the classification. However, once burned, twice shy.
Q. At Page 80 of your expert report, do you discuss the different literature and data you found to be reliable with regard to TVT and its effects on sexual function --
A. Yes.
Q. -- in addition to the AUA and the SGS guidelines?
A. Yes. (Reading:)
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published two-year results concluding that midurethral surgery for stress urinary incontinence significantly improved sexual function, and neither synthetic mesh sling route that was studied was associated with increased dyspareunia.
Q. Does the reliable scientific evidence that you have assessed on the TVT device in the intended use of treating stress incontinence when it has with the sheath and the trocars, the entire device, show that there is a significant risk of the mesh roping?
A. No.
MR. KUNTZ: Objection.
BY MR. SNELL:
Q. Or the mesh curling?
A. No.
MR. KUNTZ: Objection.
BY MR. SNELL:
Q. Of fraying?
A. No.
MR. KUNTZ: Objection.
BY MR. SNELL:
Q. Of pore collapse?
A. No.
Q. Of degradation?
MR. KUNTZ: Objection.

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THE WITNESS: No.
BY MR. SNELL:
Q. Of pore collapse?
A. No.
Q. Of a lack of biocompatibility?
A. No.
Q. And the paragraph on Page 80 of your expert report, with regard to the alleged defects that the plaintiffs' experts have raised -- you saw the different claims that the plaintiffs' experts made in their expert reports, and I'm focusing specifically on Drs. Blaivas, Dr. Elliott, and Dr. Rosenzweig.
A. Okay.
Q. Did you -- you've read their reports? You saw the claims they make?
A. Yes, yes.
Q. Do you believe that they assessed the reliable scientific literature with regard to the safety of TVT and its intended use to treat stress incontinence in formulating those opinions?
A. The level of evidence was not Level 1.
Q. And their reliance on hernia literature or non-TVT Retropubic studies, did you find those to not be relevant?
A. Not relevant to what I was tasked with

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Retropubic TVT. Retropubic TVT mesh was not used in abdominal hernia. In an abdominal hernia large sheet of mesh is not used in TVT.

Q. You were asked about, would you disagree with a surgeon who said that it was difficult to tension the mesh or -- do you recall those questions in general --

A. Yes.

Q. -- about would you disagree if a surgeon said this?

A. That's that surgeon's opinion. I may disagree with it, but it's his opinion.

Q. Right. My question to you, though, is: Would that surgeon's statement or opinion, how would that rank on the level of evidence, the evidence pyramid, compared to the data upon which you primarily relied?

MR. KUNTZ: Objection.

THE WITNESS: That would be an expert opinion, so very low level.

BY MR. SNELL:

Q. And is that called anecdotal evidence?

A. Yes.

Q. And in order to assess the overall utility and safety of the TVT device in the treatment of

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stress incontinence, you need to look at the highest level of evidence; is that what you've testified?

A. Yes.

Q. Because anecdotal evidence, case reports, do they establish causation?

A. Not at all.

Q. Can you apply those to the population abroad so that you can derive incidence?

A. No.

Q. And is it fair to say you -- I'll withdraw that one.

Are you aware of any reliable scientific literature that shows that TVT, when treating patients for stress urinary incontinence, actually does degrade?

MR. KUNTZ: Objection.

THE WITNESS: I'm not aware of any high-level evidence.

BY MR. SNELL:

Q. Or that even if one were to assume it degraded there is any clinically significant effect?

MR. KUNTZ: Objection.

THE WITNESS: I would agree that we do not see clinical effect even if it were to degrade.

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BY MR. SNELL:

Q. And is the long-term data that you cited to and you have reviewed relevant to your analysis in that regard --

A. Yes.

Q. -- if at all?

Why is that?

A. When we are looking at long-term rates, do we see an increase, do -- these are all things that are we are assessing, safety, tissue compatibility, in a very clinical aspect.

Q. And when you talk about the long-term studies, are you talking about TVT Retropubic device studies, or are you talking about some other device or application?

A. No, Retropubic TVT mechanically cut.

(Exhibit No. 17 marked for identification.)

BY MR. SNELL:

Q. I've handed a five-year randomized control trial by Laurikainen that looked at the TVT Retropubic device. Are you familiar with that?

A. Yes.

Q. This is a study you've read and relied upon?

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A. Yes.

Q. Is this a study that you considered in the formulation of your opinions in this matter?

A. Yes.

Q. And is this the TVT Retropubic device that you have been discussing that you assessed the utility and safety of here?

A. Yes.

Q. If you'd turn to the Results section. I just have a quick question. Let me ask you. Let's back up, I'm sorry. Look to the first page.

It says 95 percent of the included women were assessed at five years.

A. Yes.

Q. How does that number -- what is the significance, if anything, about 95 percent follow-up in a five-year randomized trial?

A. That -- this was phenomenal follow-up and, also, that the surgeons were able to assess these patients. There was only a 5 percent dropout rate. That's -- that's very nice.

Q. And in this study, how did the TVT perform from a utility and a usefulness standpoint?

A. I'll read the Results section. It says:

Results and limitations: A total of

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95 percent of the included women could be assessed according to the protocol five year after surgery. The objective cure rate was 84.7 percent in the TVT group and 86.2 percent in the TVT-O group, with no statistical difference between the groups. Subjective treatment satisfaction was 94.2 percent in the TVT group and 91.7 in the TVT-O group, with no differences between groups. Complication rates were low, and no difference between groups.

Q. So what does a subjective treatment satisfaction rate of 94 percent, if anything, tell you about the long-term biocompatibility of the TVT device?

A. At five years out, the patients are very happy with the results.

Q. Turn to the Results section right above Discussion.

A. Okay.

Q. You mentioned that it says complication rates were low. What's the significance of that, if anything, with regard to the safety and biocompatibility of the TVT Retropubic device?

A. That if there were problems with biocompatibility, we would start to see erosions and we would start to see pain and these kind of things.

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Q. In the paragraph above Discussion, it reports -- it says, "No women had any sign of tissue reaction, erosion, or tape protrusion at their five-year follow-up." Did I read that?

A. That is correct.

Q. What is the significance, if anything, of that?

A. That at five years out we're not seeing problems with mesh erosion or signs of infection or decreasing function.

Q. And it said, During the course of the study, two women experienced tape problems. Both were in the TVT-O arm but not the TVT Retropubic arm, correct?

A. Let me read this one:

During the course of the study, two women experienced tape problems, both in the TVT-O arm. One woman had a tape extrusion one year postoperatively. The midline visible part of the tape was excised, resulting in incontinence, and she later had a TVT operation. One woman had retention problems and the tape was cut in the midline twice, which resolved the retention, but she experienced urgency symptoms.

Q. So in this five-year -- is this a long-term study in your opinion?

A. Yes.

Q. And this five-year, long-term randomized control trial -- and, again, is that the highest level of evidence?

A. Yes, it is.

Q. Were there any tape extrusions in the TVT Retropubic group?

A. No.

Q. And what, if anything, does that inform you of with regard to the safety and biocompatibility of the TVT Retropubic design?

MR. KUNTZ: Objection.

THE WITNESS: That the design showed that there was no evidence of mesh erosions in this well-done study.

BY MR. SNELL:

Q. Does this study speak to the safety of the TVT Retropubic device in its design?

A. Absolutely, and this is actually one of the studies I quote when I talk to my patients.

Q. And is this study consistent or inconsistent with your opinion that the TVT -- strike that.

Is this study consistent or inconsistent

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with your opinion, as stated in your expert report, that the design of the Retropubic TVT is safe for its intended use to treat stress incontinence?

A. Yes.

Q. Is it consistent or inconsistent?

A. It is very consistent with my --

Q. Okay. I forgot my question. I apologize, Doctor. Sometimes I forget myself.

Plaintiffs' counsel, Mr. Kuntz, asked you questions about your experience with different design aspects of different devices, particularly, you know, devices that you had consulted on or had some involvement in the design, meeting with the engineers, things like that.

A. Yes.

Q. Were there any other devices that you have been involved in the design assessment or the safety assessment that you did not mention to Mr. Kuntz?

A. I honestly don't remember what I mentioned to Mr. Kuntz --

Q. Okay.

A. -- but with Coloplast, I was consulted on their single-incision sling with the anchoring mechanism. With AMS, I also was consulted for their anchoring mechanism on their single-incision sling.

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Dr. Stephen Singh of Australia consulted me on a Colpotomizer that he was developing and subsequently obtained FDA clearance. And then, also, with my work with LigaSure, which I think we discussed.

Q. Okay. When you provide professional education on the TVT Retropubic device, would you educate surgeons on the instructions for use?

A. Yes.

Q. Would you take surgeons step by step through the instructions of use and how to adequately and properly employ the design of the TVT Retropubic device?

MR. KUNTZ: Objection.

THE WITNESS: Yes. Also, at the, especially, cadaver labs, and things, is we actually had copies of the IFU that we would hand them.

BY MR. SNELL:

Q. Okay. You were asked some questions by Mr. Kuntz about, well, if a surgeon said that removing a mesh was difficult, would you disagree with him; do you recall a question along those lines?

A. Yes.

Q. Let me ask you this -- and I think you told Mr. Kuntz. You have done excisions of mesh slings, correct?

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A. Yes.

Q. Have you done an excision or release of the TVT Retropubic device sling?

A. Yes.

Q. Was that a difficult procedure in your experience?

A. No.

Q. Why do you say "No"?

A. I could do it in the office under local anesthetic.

But in going back to that surgeon is if they had a difficult time, I would try to offer, "Here's what I've done; this may make it easier and safer for you and your patient." And so if they would sit back and say, "Hey, I'm having a problem with this," I would say -- sit back and say, "Well, here's what I've done that made it easier," and so it's always an educational process on that.

Q. How would treating a TVT Retropubic mesh exposure compare in difficulty to having to go back and treat a Burch voiding dysfunction problem?

A. They're not -- they're not even in the same league. You know, I would bring a patient in. I did an abstract on just treating it with laser treatment in the office under local anesthetic of which none of those patients were charged.

And if there was a 1 centimeter extrusion, what I would do in those cases is I would infiltrate local anesthetic to separate the vaginal epithelium from the underlying tissues, go approximately 5 millimeters laterally and incise that tissue and infiltrate the local anesthetic on each side and remove the mesh.

Q. And I think you said -- you've published on treating tape exposures?

A. I have presented.

Q. Presented. Fine.

A. Yes.

Q. Have you published or presented on the lack of any biocompatibility in non-Type I -- Amid Type I meshes?

A. I -- the paper that I -- the case report paper would be a publication.

Q. And when you did professional education on the TVT Retropubic device, did you also assess and discuss with surgeons whether that mesh was an Amid Type I mesh or not?

A. Yes.

Q. And what, if anything, did you tell the surgeons with regard to whether or not it was an Amid

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Type I mesh?

A. Oftentimes, I go back to my Gore-Tex mesh, it was just one of those big things in your life, but what I would do is I would say that the Amid classification Type I macroporous mesh allows the body, macrophages, blood vessels, to incorporate into that tissue and actually allow it to reinforce the prior damaged tissues.

Q. The macrophages, the blood vessels for incorporation for tissue healing?

A. And fibroblasts. Yes.

Q. Is that something you learned about during your surgical training and residencies?

A. I actually had a strong interest in microsurgery early on in my career, so we did look at healing defects and trying to figure out why some women had more scarring than others. And then, again, specifically with Retropubic TVT, with that mesh, I had had very negative experiences with Marlex mesh, Mersilene, and I was very hesitant.

Q. How does the strength of the evidence and the medical literature, assessing the safety and utility of TVT, compare to the literature assessing Burch and autologous?

MR. KUNTZ: Objection.

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THE WITNESS: Most of the Burch and autologous slings are case series expert opinion which would be low-level evidence.
BY MR. SNELL:
Q. Is the TVT evidence of a higher level overall than the Burch or autologous pubovaginal slings if one looks across --
A. If you look at --
Q. -- the reliable literature?
A. If you look at the total number of RCTs, et cetera, overwhelmingly Retropubic TVT has the highest-quality evidence.
MR. SNELL: Okay. Thank you.
REDIRECT EXAMINATION
BY MR. KUNTZ:
Q. Doctor, just a couple of questions.
You went over, again, these mental lists you keep of how many surgeries you've performed and these mental logs of how many erosions you've had and mental logs of reoperations, correct?
A. Yes.
Q. So you're good at keeping mental logs over a ten-year period of time of your surgeries --
A. Yes.
Q. -- revisions, correct?

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A. Yes.
Q. Okay. What's your mental log tell you of how much you've been paid by Ethicon over the last 11 years as an consultant?
A. Because I did not see those checks, that went to my office manager and accounts. I --
Q. Who was your office manager.
A. Arlone Farber.
Q. She's still your office manager?
A. No.
Q. So --
A. When I took my --
Q. So you don't have a mental log of how much money you've made from Ethicon over the last 11 years?
A. No, I do not.
Q. That's just a mental log you don't keep like you do everything else?
A. Correct.
Q. Okay. You had said you'd worked with some engineers as an end user of the TVT Retropubic device?
A. Yes.
Q. What engineers?
A. What's Dan -- Dan Smith would be one. The

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engin- -- I don't recall the name of the engineers at Coloplast or at AMS.
Q. Okay. How many meetings did you have with Dan Smith about the TVT Retropubic device?
A. Formal meetings and when I was there to talk with him?
Q. Let's start with formal.
A. I don't think on TVT Retropubic I had any formal meetings with him.
Q. Okay. What about informal meetings?
A. I would sit down and talk with him, especially I wanted to find out how they came up with the design of the trocar, how they chose the angles; I was just fascinated by those things and, you know, the cadaveric studies and these things. I wanted to know a little bit more about that.
Q. You had cited some RCTs and went over them on Page 39 of your report.
A. Okay.
Q. Tell me which one of those RCTs is laser cut mesh and which one is mechanical cut mesh.
A. We can -- the older ones would all be mechanical cut.
Q. What do you mean by "older"?
A. So we would talk about Ward, Valpas, Lee.

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I would have to look at Rinne and Palva on whether they -- their data was gathered pre-2007.
Q. So as we sit here today, you don't know whether Rinne, Palva, Laurikainen, Wai, Khan, or Ross involved laser cut or mechanical cut mesh, correct?
A. That is correct.
Q. And you've kept your documentation of the money you've made from Ethicon for the last seven years you told me, correct?
A. I think it would be available. I don't personally have it.
Q. Okay. But you can get the last seven years?
A. I believe I can.
Q. Okay. You had said that you consult -- or --
MR. SNELL: I'm going to object to producing that, but that's just for my record.
THE WITNESS: Okay.
(Discussion off the record.)
MR. KUNTZ: I'm not talking about 1099s. We're talking about summations. And if you want to do that, then we'll -- let's just -- let's go gold, man, let's just go all of them. I'll do a trade any day of the week you want to do it for our

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guys for your people.
MR. SNELL: That would get your boy Dan Elliott fired who claims he's supposed to be working as an expert.
MR. KUNTZ: Do something about it. Talk is cheap.
MR. SNELL: I'm not a dirty pool player.
BY MR. KUNTZ:
Q. Doctor, you told me that you consulted with your patients and you tell them about the 11- and 17-year data.
A. Yes, I did.
Q. Do you tell your patients that?
A. Yes, I do.
Q. Okay.
A. And when it was earlier data, I would sit back and say, "This is the longer follow-up on these."
Q. Okay. Do you tell them that when you're advising them to have the TVT product implanted?
A. I -- I inform them that there is studies up to 11 -- 17 years --
Q. Okay.
A. -- that have --

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Q. And do you tell them that in your office or the day of the surgery?
A. In my office.
Q. Okay. So you tell your patients that may end up getting the laser cut mesh that there's 17-year data to support it?
A. What I tell them is that with the TVT products --
Q. Oh, okay.
A. -- that there's up to 17-year data.
Q. Okay. Do you tell them that the 17- and 11-year data doesn't apply to laser cut that they might get but you won't know until the day of the surgery that they're getting laser cut?
A. No, I just say the TVT products.
Q. Okay. Do you think that's fair? Do you think it's fair to tell your patient that there's 17- and 11-year data when that data doesn't exist for laser cut mesh?
MR. SNELL: Objection, misstates.
BY MR. KUNTZ:
Q. Well, let's walk through this, Doctor. You tell them in your office before they get to surgery that there -- for the TVT products there's 17- and 11-year data?

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A. There's data up to 17 years.
Q. Okay. Do you tell them that they might be getting a laser cut mesh that doesn't have 17-year data to support it?
MR. SNELL: Objection, form.
THE WITNESS: No, I just say the TVT products.
BY MR. KUNTZ:
Q. Okay. Do you tell them after that --
A. No.
Q. -- after you find out you give them the laser cut mesh?
A. No.
Q. Do you go back and tell them, "Hey, I was wrong. You got the laser cut mesh. There's not 17-year data to support it"?
MR. SNELL: Objection: Argumentative, misstates. He's already told you it's the same mesh, regardless in his opinion. So you're trying to make a mountain out of a molehill.
BY MR. KUNTZ:
Q. No. You know -- you said the 17-year data and 11-year data does not apply to the laser cut mesh earlier today in this deposition, did you not?
MR. SNELL: I think that misstates his

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testimony.
BY MR. KUNTZ:
Q. Did you not say that?
A. I believe that it does not and --
Q. Okay. Do you go back and tell your patients they got a laser cut mesh, that you don't know -- you said, under oath, that you don't know until the day of the surgery they're getting laser cut mesh. Do you go back and tell them that the 17- and 11-year data doesn't support the product that you implanted?
MR. SNELL: Objection, form.
THE REPORTER: No, I don't.
MR. KUNTZ: Okay. No more questions.
RECROSS-EXAMINATION
BY MR. SNELL:
Q. In your opinion, is the mechanical and laser cut mesh the same regardless of the way you cut it?
A. Yes.
Q. And is that why you cite to 11- and 17-year data for the TVT devices?
A. Yes.
Q. And if you look at your expert report--I'm glad Mr. Kuntz brought this up--you actually list the

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chronology of different data on the TVT devices, don't you?
A. Yes.
Q. And, actually, can you tell Mr. Kuntz, on Page 39, whether the older studies and the longer-term mechanical cut mesh, whether those rates are any different than the newer studies or are they the same?
A. That's --
Q. Can you answer my question, first: Are they the same or are they different?
A. Yes, they are.
Q. "Yes, they are" what?
A. They are the same.
Q. All right. And what is the significance of that to you in the question of whether it matters clinically if their mesh is mechanical or laser cut?
A. It does not matter clinically.
Q. And from 1999 until 2007, every single TVT mesh Retropubic device that you implanted, were those mechanical cut or laser cut?
A. Mechanical cut.
Q. And since 2008, have you implanted both?
A. Yes.
Q. All right. And I think you told Mr. Kuntz

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you could see the difference, you could tell the difference because you worked with a mesh right up close when you're considering implanting it?
A. It's in my hands and I am looking at it.
Q. And did you ascertain any difference whatsoever in the implantation of a laser cut versus a mechanical cut mesh?
A. No.
Q. And I think you told me that they're both covered and encased by a sheath, right?
A. Yes.
Q. And have you assessed or found any difference in complications in those meshes?
A. No.
MR. SNELL: No further questions.
(4:21 p.m. - Adjournment.)
§ § §
(Signature reserved.)

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C-E-R-T-I-F-I-C-A-T-E

STATE OF NEBRASKA)
) ss.
COUNTY OF OTOE)

I, Sondra W. Petersen, RMR, CRR, CSR(IA), and General Notary Public in and for the State of Nebraska, do hereby certify that MICHAEL P. WOODS, M.D. was by me duly sworn to tell the truth, the whole truth, and nothing but the truth; that the deposition as above set forth was reduced to writing by me.

That the within and foregoing pages were taken by me at the time and place herein specified and in accordance with the within stipulations; that the foregoing deposition is a true and accurate reflection of the proceedings taken in the above case.

That I am not counsel, attorney, or relative of either party or otherwise interested in the event of this suit.

IN TESTIMONY WHEREOF, I place my hand and notarial seal this 6th day of October, 2015.

SONDRA W. PETERSEN, RMR, CRR, CSR
GENERAL NOTARY PUBLIC

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INSTRUCTIONS TO WITNESS

Please read your deposition over carefully and make any necessary corrections. You should state the reason in the appropriate space on the errata sheet for any corrections that are made.

After doing so, please sign the errata sheet and date it. It will be attached to your deposition.

It is imperative that you return the original errata sheet to the deposing attorney within thirty (30) days of receipt of the deposition transcript by you. If you fail to do so, the deposition transcript may be deemed to be accurate and may be used in court.

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I,_____, do hereby certify that I have read the foregoing pages, and that the same is a correct transcription of the answers given by me to the questions therein propounded, except for the corrections or changes in form or substance, if any, noted in the attached Errata Sheet.

_____

MICHAEL P. WOODS, M.D. DATE

Subscribed and sworn to before me this _____ day of _____, 20____.

My commission expires:_____

_____

Notary Public

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